health

Department:
Health
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Policy for the Regulation of Quality Respiratory Protective Equipment (RPE) Supply in Healthcare

This policy is developed by the National Department of Health (NDOH) Occupational Health & Safety (OHS) Quality Assurance Committee in conjunction with the South African Health Products Regulatory Authority (SAHPRA) and the National Regulator for Compulsory Specifications of South Africa (NRCS)

OVERVIEW

The intention of this policy is to ensure that all health workers in South Africa are afforded access to quality respiratory protective equipment, and in particular half face particulate respirators. This translates into best protection against COVID-19, TB and any other respiratory infectious disease during and post COVID-19 pandemic. Such protection ensures our already under-resourced human resource health sector is not further denuded through illness and that patients are afforded access to quality healthcare.

Therefore, this policy and the associated technical information are provided to ensure that new respirators and respirators already in circulation are checked to meet industry quality standards.

The interventions introduced through this policy are a collaborative and innovative mechanism to incentivise provision of quality respirators at the point of use. Mechanisms herein incentivise suppliers, purchasers and facilities across the public and private sector to ensure quality and appropriate products are purchased (local or imported) and that they are readily available in sufficient supply to meet demand.

Local manufacture and procurement are prioritised and encouraged – whether finally distributed locally or abroad.

I express special appreciation to the PPE Committee, SAHPRA, SABS, NRC, Department of Trade and Industry member of the Ministerial Advisory Committee who participated in the drafting and review of the guideline and provided insightful comments and direction.

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Date: 2020/10/29

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DEFINITIONS IMPORTANT TO THIS POLICY:

1. Respiratory Protective Equipment (RPE) for this policy includes Class A and Class B devices as registered by SAHPRA and specifically references half face particulate respirators:

   Class B: "N95", "KN95", "FFP2", and "FFP3" single use disposable filtering facepiece respirators categorised as Class B medical devices by SAHPRA.

   Class A: Medical (Surgical) Face Masks, e.g. 3-ply masks, as categorised by SAHPRA. There is a further delineation into Class A sterile and Class A non-sterile categories.

2. Regulatory Standards

   Regulatory bodies such as the Centres for Disease Control (CDC), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), American Conference of Governmental Industrial Hygienists (ACGIH), British Safety Industry Federation (BSIF), etc., refer to a particulate respirator (whether FFP2/N95, etc.) as one that is approved and compliant to Personal Protective Equipment (PPE) regulatory requirements (homologation and legislative).

   Examples of comparable International and Local Standards for Filtering Facepiece Respirators (FFRs) include:

- South Africa: SANS1866-2:2018, SANS50149:2003, SANS50143:2003, SANS10338:2009, SANS10220:2010, SANS50136:1998
- Australian Standards: AS/NZS1716:2012 & AS/NZS1715:2009
- European Union Standards: EN149-2001 & EN529:529:2005
- United States: NIOSH Approval 42CFR84 & OSHA29CFR1910.134
- China: Standard effective 01-07-2020: GB 2626-2019 & GB19083:2010

NIOSH has published a list of "respirators approved under standards used in other countries" that NIOSH considers of similar quality to US approved N95 respirators. This list is available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html).

3. Quality

Quality RPE that meets the defined and required standards are detailed as follows:

- All Filtering Facepiece Respirators (Particulate Respirators), regardless of originating territory, are expected to meet the South African Standard of SANS1866-2:2018 with inward leakage standard compliance and/or SANS50149:2003. These standards provide reference but do not ensure that the respirators definitely meet the required South African standard.
- Importantly, SANS 50149 is the standard for non-medical respirators with comparative qualitative filtering efficiency and applies to respirators accredited and recognised by the National Regulator for Compulsory Specifications (NRCS). This may include N95, FFP2, FFP3, or KN95. This standard is not a medical standard with the result that these respirators may or may not provide fluid resistance or sterility for surgical procedures.
- Medical (surgical) face masks, sterile and non-sterile, SANS 1866:2018 Part 1, are for use by health workers and must meet this standard irrespective of whether the supplier is registered as a device establishment with SAHRPA.

Please note that EN149 and EN14683 are European standards relating to a wide variety of medical masks and respirators. On this basis their listing on RPE does not allow for determination of whether the RPE is Class A or Class B device with attendant performance required of each Class.

4. Overview Classification of Medical Devices by SAHPRA

Classification	Level of risk
Class A	Low risk
Class B	Low–moderate risk
Class C	Moderate – high risk
Class D	High risk Where risk relates to the patient or to public health

PROBLEM STATEMENT

The supply and distribution of appropriate quality protective RPE (and all PPE) for frontline health workers is a challenge for all healthcare systems.

South Africa faces unique challenges with respect to global supply and quality assurance of PPE with:

- Limited ability to provide optimum, large scale and rapid regulatory testing prior to distribution;
- Legal, regulatory and practical barriers (including logistics and sheer numbers) to provide a centralised database published repository of PPE testing, quality and type through SAHPRA as the national regulator;
- Many competing incentives (financial, political, supply and demand, manufacture, and import) and demands on government to enable rapid distribution of PPE that may not align to dynamic requirements informed by the pandemic and beyond.

As a result of these challenges, the country has been dealing with a significant number of both imported and locally manufactured respirators that have failed to meet the relevant SANS, verified through testing by accredited South African laboratories. While many respirators that do not meet the listed standards were identified prior to distribution, many still found their way to facilities and health workers.

The South African healthcare system is under extreme pressure. Outside of the economic considerations of this pandemic, we are particularly stressed from a human resources perspective.[1] The number of medical doctors, specialists[1] and nursing personel[2] are inadequate to serve the needs of our population, even when combining the public and private sectors.[1,2] The severe pressure on our healthcare system as a result of the human resource ratio to the population[1,2] naturally results in higher workloads and increased exposure to infected patients per health worker (more patients seen per shift).

Furthermore, our national healthcare human resources rely on a significant number of older health workers who have more co-morbidities than younger health workers. Older health workers have attendant co-morbidities and an incidence of obesity that is also higher than international norms.[7]

The South African healthcare system cannot afford any preventable loss of health workers to preventable illness - during the COVID-19 pandemic, the TB pandemic or any future pandemic.

DISCUSSION

At the early stages of the pandemic, Professional Societies, Business for South Africa (B4SA) and the NDOH attempted to establish a national supply and distribution network for PPE. The vision was and remains that no health worker should fall ill owing to inadequate access to quality PPE and no patient not afforded care because of PPE inaccessibility. This structure had limited success for various reasons beyond the scope of this advisory. That stated, the intention was to ensure PPE supply and distribution were secured, competition for PPE within the healthcare sector was avoided, all health workers accessed necessary quality PPE whenever needed, and a mechanism to ensure quality was at the forefront of the supply system.

Quality PPE, especially particulate respirators, were identified as vital to protect against high viral and bacterial loads encountered in delivering care to symptomatic COVID-19 or TB patients.

In "COVID-19 Risk Factors Among Health Workers: A Rapid Review"[3], the following five risk factors were identified:

1) lack of personal protective equipment (PPE)
2) exposure to infected patients
3) work overload
4) poor infection control
5) pre-existing medical conditions

Further, a mathematical modelling study by Temime et al. found that R0 for COVID-19 was higher for health workers who have prolonged contact with infected individuals as compared to the general public.[4] Similarly, health workers are at a three times increased risk of acquiring drug-sensitive TB[5] and six times greater risk for acquiring drug resistant TB[6] as compared to the general population.

Of the 5 risk factors cited, quality PPE supply to the healthcare sector and poor infection control practice need to be immediately addressed. Quality assurance is vital to avoid unnecessary infection as inferior quality PPE will have a direct influence on the incidence of health worker illness.

The NDOH, together with NGOs and professional societies, is addressing communication and training platforms to improve infection control, but quality PPE distribution remains a challenge that requires intervention at a higher level.

In support and recognition of ensuring quality national PPE supply and distribution, Treasury issued Treasury Note 3 that enforced a central emergency procurement strategy. The merits or demerits of this, as well as the reasons for this note's repeal, are beyond the scope of this advisory.

Treasury Note 5 of 2020/21[8] then enabled local procurement of PPE within the framework of emergency procurement under the Public Finance Management Amendment Act (PFMAA) and up to a value of R30 million on a decentralised basis by provinces. Provincial

acquisition without oversight enables procurement (not necessarily intentionally) of products that did not meet quality standards.

The unfortunate consequences have been:

1. A failure to enable oversight on procurement of PPE at best price;
2. A failure to prioritise local manufacture and supply over imported goods;
3. An inability to ensure that all PPE supplied to facilities or health workers can be checked to ascertain that it meets specific quality standards;
4. Some procurement tenders to supply PPE to the State awarded to companies with limited or no expertise and experience in medical and related fields making them vulnerable to supply of inferior quality products and;
5. That no mechanism exists to ensure information regarding failed testing as it relates to quality, is shared in the public domain to enable nationwide protection of health workers.

The production, sale and supply of PPE has been further hampered by fake or falsified certification. This is a global problem and South Africa is not being spared.

Particulate Respirators – RPE

Particulate respirators (FFP2, N95, KN95 or better) are recommended internationally and by our National Institute For Communicable Diseases (NICD) for health workers for aerosol generating procedures (AGP)[9] or airborne exposure in the context of infectious diseases such as COVID-19 and TB – particularly in confined and/or poor ventilated environments.

Any RPE used in occupational respiratory risk zones are required to meet local (and therefore international equivalent) PPE regulatory requirements. This includes, but is not limited to, healthcare service provision in high risk areas (COVID-19 high care and intensive care units). Recent data and prior national TB prevention guidelines support the provision of quality "filtering facepiece respirators" (certified FFP2, N95 or better) to prevent health worker infection from COVID-19[10,11,12] and TB[13,14,15].

The immediate imperative is in ensuring the minimum number of health workers become infected with COVID-19 in the workplace. We have an extremely under-resourced healthcare system to service the needs of our country. Protecting our workforce to deliver the greatest capacity of services during this pandemic (and other current epidemics such as TB) is critical.

The following examples exist with respect to respirator supply and distribution in South Africa:

- **New Particulate filtering facepiece respirators** purchased and/or distributed and later tested failing to meet specified standards (either national and/or international (SANS1866-2:2018; SANS 50149:2003, SANS 10338:2009 or earlier referenced standards for approved N95, KN95, FFP2 or FFP3).

- **Extended use, re-use and sterilisation** being market driven for single-use devices without regulatory approval and without any form of "post sterilisation/re-use" surveillance testing.
- **Class A non-sterile medical masks** (SANS 1866-1:2018) imported and locally manufactured with establishments being exempted[17] from SAHPRA registration and then marketing these masks as equivalent or superior to Class B registered and approved respirators (SANS 1866-2:2018).

REGULATORY AND LEGAL REFERENCE INFORMING THE POLICY

1. SAHPRA Regulations

For Medical (Surgical) Masks and Particulate filtering facepiece Respirators[16]

- **A medical device may only be manufactured, imported, exported, distributed, or wholesaled by a medical device establishment that holds a valid medical device establishment licence issued by SAHPRA, in terms of Section 22C(1)(b) of the Medicines Act.**
- Face masks fall into different regulatory groups depending on the type of face masks and intended use of the face masks. Refer to infographic in Annexure 1 for a summary of the types of masks, regulatory requirements and intended purpose:
    - General
    - Medical (Surgical) Masks Non-Sterile
    - Medical (Surgical) Masks Sterile
    - Particulate Respirators
- Class A Medical Devices
    - Includes non-sterile medical (surgical) masks and sterile medical (surgical) masks, such as a 3-ply masks intended for use in a clinical environment, are controlled under the ambit of the Medicines Act and fall within the mandate of SAHPRA.
    - However, manufacturers, distributors and wholesalers of non-sterile Class A medical devices are excluded from licensing requirements. They are still classified as medical devices however, the manufacturers, distributors and wholesalers of non-sterile surgical masks do not require a section 22C(1)(b) license from SAHPRA.
    - Manufacturers, distributors and wholesalers of sterile surgical masks must comply with the licensing requirements.
    - Sterile and non-sterile surgical masks must be tested according to and certified against, the SANS 1866-1:2018 "Medical Devices Part 1: Medical Face Masks" and SANS 50149:2003 or the equivalent international standards, as well as the Legal Metrology Act, 2014 (Act 9 of 2014), in terms of packaging and labelling. SAHPRA may declare conditional exclusions of and modifications to the tests of SANS 1866-1:2018 for South African manufacturers.

- **Class B Medical Devices**
  - **A particulate respirator intended for use in a clinical environment, is categorised as a Class B Medical Device by SAHPRA and is controlled under the ambit of both the Medicines Act and the National Regulator for Compulsory Specifications (NRCS) Act.**
  - Manufacturers, distributors and wholesalers of respirator masks must comply with SAHPRA's licensing and NRCS requirements.
  - Manufacturers, importers and distributors of respirator masks and particle filtering half masks (respirators) intended for use in a non-clinical environment must apply for pre-approval from the NRCS to ensure compliance against the minimum requirements set out in the Compulsory Specification for respiratory protective devices – VC8072:2011 – as published by Government Notice No. R. 407 (Government Gazette No. 34272) of 13 May 2011 and the relevant SANS standards on Respiratory Protective Devices:
    - SANS 10338:2009 "Homologation of Respiratory Equipment"
    - SANS 50149:2003 "Respiratory protective devices - Filtering half masks to protect against particles"
    - SANS 50136:1998 "Respiratory Protective Devices - Full Face Masks"
    - SANS 50143:2003 Respiratory Protective Devices – Particle Filters".
  - Manufacturers, importers and distributors of RPE must also apply for pre-approval from the NRCS to ensure compliance against the minimum requirements set out in the International RPE requirements for Compulsory Specification for respiratory protective devices – VC8072:2011, as published in Government Notice No. R. 407 (Government Gazette No. 34272) of 13 May 2011 and the SANS 1866-2:2018 "Medical devices Part 2: Medical Respirators" and the relevant SANS of Respiratory Protective Devices.
  - Therefore, **a respirator mask, intended for use in a clinical environment, requires pre-approval from the NRCS**. The manufacturer, distributor, or wholesaler of said mask, requires **licensing approval from SAHPRA as a device establishment**.
  - Depending on the intended use of the RPE and the environment in which the RPE is used, respiratory protective devices are also subject to the provisions of the following Acts:
    - National Regulator for Compulsory Specifications Act (2008)
    - Mine Health and Safety Act (Act 29 of 1996)
    - Occupational Health and Safety Act (Act 85 of 1993)

2. The Consumer Protection Act of 2008[18]

The Consumer Protection Act of 2008 stipulates the following with respect to the "Consumer's right to return goods" and applicable to the recommendations, under section 20 of the Act:

20. (1) This section is in addition to and not in substitution for—

(a) the right to return unsafe or defective goods, contemplated in section 56; or

(b) any other right in law between a supplier and consumer to return goods and receive a refund.

(2) Subject to subsections (3) to (6), the consumer may return goods to the supplier, and receive a full refund of any consideration paid for those goods, if the supplier has delivered—

(d) goods intended to satisfy a particular purpose communicated to the supplier as contemplated in section 55(3), and within 10 business days after delivery the consumer, the goods have been found to be unsuitable for that particular purpose.

(4) Goods returnable in terms of— (b) subsection (2)(b) to (d) must be returned to the supplier at the supplier's risk and expense, within 10 business days after delivery to the consumer.

(5) Upon return of any goods in terms of this section, the supplier must refund to the consumer the price paid for the goods, less any amount that may be charged in terms of subsection (6).

(6) In determining the right of a supplier to impose a charge contemplated in subsection (5), if any goods returned to the supplier in terms of this section are—

(a) in the original unopened packaging, the supplier may not charge the consumer any amount in respect of the goods;

(b) in their original condition and repackaged in their original packaging, the supplier may charge the consumer a reasonable amount for—

(i) use of the goods during the time they were in the consumer's possession, unless they are goods that are ordinarily consumed or depleted by use, and no such consumption or depletion has occurred; or

(ii) any consumption or depletion of the goods, unless that consumption or depletion is limited to a reasonable amount necessary to determine whether the goods were acceptable to the consumer.

3. Procurement of Local Products

Attention and reference are directed to the Preferential Procurement Policy Framework Act 5 of 2000 ("PPPFA") with specific reference to Regulation 8 (Local Production and Content) of the regulations gazetted 20 January 2017. Respirators (and the majority of PPE) are listed under "Clothing and Textiles" as a "Designated Product" for 100% local production and procurement. This means that all procurement of respirators is subject to the local content requirements of the Act and Regulation 8 of the 2017 Preferential Procurement Regulations of 2017.

This policy applies to public sector (Provincial and National) procurement of all respirators that are used for the purposes of protection of health workers and in accordance with NICD guidelines. This means that all locally manufactured respirators (FFP2, FFP3, N95 or KN95) meeting SANS 1866-2:2018 with inward leakage test or SANS 50149:2003 for appropriate use for health workers must be considered and procured prior to any possibility of procurement of imported products in the public sector.

Respirators manufactured locally will be labelled as FFP2 or FFP3 standard and should meet SANS 1866-2:2018 including total inward leakage standard compliance and/or SANS 50149 as a minimum with specific testing requirements and standards as detailed in point 6. of New RPE supply in this document.

This document acknowledges that the PPPFA does not apply to private sector procurement. The consequence of the regulation hereunder makes local procurement advisable with legal, practical, consumer protection and regulatory parameters taken into account.

It remains our collective responsibility to ensure local manufacture and supply are supported and secured for this and future outbreaks, as well as developing the scope and capacity to support our continent. Specific reference and attention are drawn to Annexure 4 – Note from the Department of Trade Industry and Competition (DTIC) – which elaborates further on our national Re-imagined Industrial Strategy, Industrial Policy and Procurement Legislation.

4. Fit Testing

Qualitative or Quantitative fit testing (see section "All Respirators issued to Health Workers" below) should be carried out at least once annually for every health worker who is required to wear a particulate respirator, for each brand or type of particulate respirator provided.

POLICY PREAMBLE

This policy specifically takes into account the current context of supply, procurement and distribution of filtering facepiece respirators (N95, KN95, FFP2) to health facilities. It enables a **system that requires responsibility to be taken by the last point of distribution of any respirator to a health worker and makes any supplier and/or procurer of a respirator at the last point in the chain directly responsible and accountable for ensuring quality is met.**

Aligned with this policy, the purchase of locally manufactured respirators that have been tested to meet SANS 1866-2:2018 standards with total inward leakage standard compliance and SANS 50149:2003 (see *"Regulations New RPE: 6. Certification"* below) is highlighted for public sector procurement under the PPPFA. As stated earlier, private sector procurement of locally produced quality respirators is also advantageous over procuring imported product.

The consequence of not following the regulations of the PPPFA has practically resulted in large quantities of imported respirators failing to meet filtration and other standards of SANS 1866-2:2018 and/or SANS 50149:2003. This has resulted in the required removal and quarantine of this stock from warehousing and even from facilities where the stock has been distributed – in the public and private sector.

It is important to consider that RPE may provide filtration efficiency as designated by the RPE classification (e.g. N95 = 95% filtration of particles greater than or equal to 0.3 microns) but may not be resistant to blood spatter or exposure to other bodily fluid. For this reason, it is recommended that where sterility is a requirement (e.g. surgical fields), only fluid resistant rated RPE is utilised (e.g. designation N95s rather than N95). Respirators in this category may be designated as "medical respirators", "healthcare respirators", "surgical respirators" or may be clearly marked as "fluid resistant".

This policy enables, in conjunction with SAHPRA as the recognised regulator, a multipronged approach to address three key components relating to particulate filtering facepiece respirators:

1. The first component relates to new respirator sales and distribution;
2. The second relates to respirators already distributed where quality is unknown or questionable; and
3. The third relates to the practice of extended use, reuse, and decontamination – should this need arise and be approved by the regulator in future.

The NDOH with SAHPRA will publish, if necessary, further notices on post marketing surveillance, public and sector wide communication, and collaborate with other authorities including Department of Trade, Industry and Competition (DTIC) and Port Authorities.

POLICY: NEW RESPIRATORY PROTECTIVE EQUIPMENT (RPE)

To ensure quality, this policy apply to the entire healthcare sector for all purchases of filtering facepiece (particulate) respirators:

1. Publish: SAHPRA immediately publish a statement that prevents import, supply and distribution of respirators or any masks that "appear to be a respirator" (and clearly not a non-sterile facemask exempt from device establishment license with SAHPRA). Any respirator or mask that could possibly be used in a clinical environment may only be supplied by a company licensed with SAHPRA as a medical device establishment as well as compliance with Class B medical device regulations and SANS for Respiratory Protective Devices. Specifically, effort expended to prevent import, distribution and sale of "respirators" to purchasers under Class A unlicensed non-sterile medical masks.
2. Notification to all Purchasers (public and private): that medical face masks must comply to SANS 1866-1:2018 and that Class B particulate respirators supplied in the clinical environment must adhere to medical device establishment licensing requirements as per the Medicines Act and comply to SANS 1866-2:2018 with total inward leakage standard compliance and/or SANS 50149:2003 or the equivalent global standards.
3. Media Release: SAHPRA and the NDOH issue a media release and publication of requirements to identify a particulate facepiece respirator (Class B device) for end users and purchasers in the health or clinical environment, as well as require reporting by any party of poor quality or suspect respirators to SAHPRA and the NRCS as the regulatory authorities. Reports should be enabled through a SAHPRA dedicated e-mail address guaranteeing anonymity under the Protected Disclosures Act 26 of 2000 and specifically the Protected Disclosures Amendment Act 5 of 2017.
4. Sensitisation of Port Authorities regarding respirator identification and quarantine seizure of any masks that appear to be respirators but are not described as such on import documentation.
5. Batch Verification: Outline requirements for all respirator (Class B) manufacturers or importers to use South African accredited laboratories through the South African Bureau of Standards (SABS) with this list to be provided on SAHPRA's website and in accordance with SAHPRA specified requirements. These accredited laboratories will be authorised to conduct testing to ensure RPE meets the relevant SANS standard applicable to its marketing and registration. This should **be conducted prior to distribution of goods.** Where increased testing capacity is required this should be facilitated and assisted by the SABS, NRCS, SAHPRA and DTIC.
6. Certification: **All particulate filtering facepiece respirators** sold should be accompanied by Homologation Certificates, proof of international compliance (in the case of imported RPE including NIOSH approvals, European Union certifications, CE marking reports and complete FDA registrations) and quality certificates. The minimum required stipulation is:

a. Determination of Particulate Filter Penetration (PFP) with the minimum testing requirement being to NaCl filtration (and where possible to paraffin oil and latex particle);[19]
b. Determination of Flow Resistance (inhalation resistance at a minimum, but preferably inhalation and exhalation resistance with the latter mandatory for valved respirators);[19]
c. Total Inward Leakage (laboratory) and Qualitative Fit tests (performed at facility level on individuals – See Fit Testing in this document);[19]
d. Flammability Testing;[19]
e. Fluid Resistance Test (this test is not mandatory at this time owing to capacity and development constraints in lab testing in South Africa). Where fluid resistance testing has not been conducted by a verified international lab but all other local tests pass, recommendation is for mandatory visor usage to protect against respirator fluid exposure.[19]

It is important to note that the minimum standard and required testing (6 a. through e.) are a combination of SANS50149:2003 and SANS1866-2:2018 to ensure quality respirators reach our healthcare workers in the interest of their safety and patient care. This is considered the minimum legal specification any respirator must meet to be marketed, sold or used for clinical care in South Africa.

Specifically, respirators that comply with SANS 1866-2:2018 that do not pass the total inward leakage standard under SANS 50149:2003 should not be considered for clinical use.

Technical required information should also include risk analysis and information about the product, the production control of the product, user instructions, and other technical specifications.

All licensed device establishments should be published on the SAHPRA website. All respirator certificates should be verified and published on the SAHPRA website or have a link to the NRCS website in conjunction with NRCS as stated below in point 7.

All Medical (Surgical) 3 ply Masks (Close fitting masks) must be accompanied by a Quality Certificate that indicates the masks comply to SANS1866-1:2018. As of this date, with limited local accredited testing laboratory capacity, medical mask certificates tested locally should indicate a minimum standard as a combination of SANS 1866-1:2018 and SANS1866:2008 with the following requirements as a minimum for medical 3 ply masks:

a. Determination of Particulate Filter Penetration (PFP) with the minimum testing requirement being to NaCl filtration with a limit of 26% (and where possible to paraffin oil and latex particle) – SANS1866:2008
b. Determination of Breathability (differential pressure) – SANS 1866:2018

c. Water adsorption rate (indicator of fluid permeability/imperviousness) – SANS 1866:2008
d. Flammability testing – SANS 1866:2018

Metrology Notification Requirement: From the date of this publication, the following is required for all Medical (surgical) face masks (SAHPRA Class A devices) and all Filtering facepiece respirators (SAHPRA Class B device) in the interests of identification, safety and ensuring homologation is possible and accurate:

A clear physical marking/stamp on each mask or respirator with the mandatory minimum information being (all mandatory items in bold):

1. **Manufacturer/Brand name/Registered trademark** or easily understood abbreviation.
2. **For Respirators the mask or respirator efficiency classification** an alphanumeric rating as recognised (e.g. FFP2, FFP3, N95, KN95);
3. **Standard Compliance Label** that indicates the local SANS standard showing the device has been tested against and passed (e.g. SANS 1866-1:2018 or SANS51049:2003 etc.) *or equivalent* international standard that the respirator has been tested against and passed (e.g. EN149-2001 or GB2626:2019 etc.);
4. **Size of the Respirator, model number and lot number**;
5. **Any other mandatory markings** as required by SANAS, NRCS, SAHPRA, other national regulator or standard and as may be required by the Legal Metrology Act, 2014 (Act 9 of 2014).

All mask or respirator packaging per minimum quantity sold (e.g. 20 per box, or 5 per blister pack) must contain the following minimum information in addition to the mandatory requirements for masks/respirators:

1. Mandatory package standards already in place under the Legal Metrology Act, 2014 (Act 9 of 2014) in terms of packaging and labelling;
2. SAHPRA establishment license number enabling sale of Class of Device (Medical mask Class A and Respirator Class B);
3. Size of Respirator, Lot and Batch number;
4. Mask/Respirator manufacture and expiry date;

7. SAHPRA Website: SAHPRA will publish the following data on its website in the interest of public information dissemination for current RPE in circulation:
   a. NIOSH/National Personal Protective Technology Laboratory (NPPTL) has conducted and registered over three hundred international mask assessments for non-NIOSH-approved products on the market (markethttps://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html). The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. Only particulate filter efficiency was assessed.

b. A register of NIOSH-Approved N95 Particulate Filtering Facepiece Respirators that can be accessed from the following link: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect3.html. The table provides alphabetically (by manufacturer) listed NIOSH-approved N95 respirators.

c. A notice for manufacturers and importers that respirators imported and/ or manufactured with ear loop fasteners have in significant numbers:
   i. Failed to meet the required SANS 1866-2:2018 and/ or SANS 50149:2003 filtration standards;
   ii. Ear loop material is inconsistent (variable from inelastic cotton to poor quality plasticised elastic) resulting in poor qualitative fit as well as poor quality fixation between loop and respirator, proved to be extremely difficult to achieve (if even possible) qualitative fit for health workers, and;
   iii. Have generally been imported/ distributed in one size which only caters for a section of the health worker population and compromises qualitative fit.

   Accordingly manufacture/import of new particulate respirators with ear loop fasteners is prohibited.

d. Database Class B Devices – Particulate Respirators: The NRCS establishes and documents a homologation database of respiratory protective equipment for all facilities as required by the General Safety Regulations under the Occupational Health and Safety Act of 1993 of SAHPRA-registered Class B medical respirators that are considered as meeting the SANS 1866-2:2018, SANS 10338:2009 "Homologation of Respiratory Equipment", SANS 50149:2003 "Respiratory protective devices (filtering half masks to protect against particles)", SANS 50136:1998 "Respiratory Protective Devices (full face masks", and SANS 50143:2003 "Respiratory Protective Devices (particle filters)". This list is partially available as the NRCS Register on Homologation Database. SAHPRA will establish a website link to the database to be available on the NRCS website with further development of this database to be maintained in perpetuity for Class B respirators.

e. Database respiratory equipment: The NRCS establishes, documents and maintains a homologation database of respiratory equipment as required by the General Safety Regulations under the Occupational Health and Safety Act of 1993. The document should include a list of currently registered manufacturers, importers and distributors of respirator masks and particle filtering half mask respirators intended for use in a non-clinical environment. This includes those currently registered that may be utilised in a clinical environment or another suitable environment (e.g. not for use in a sterile environment with due care taken to avoid blood spatter (e.g. visor mandatory). SAHPRA will establish a website link to the database to be available on the NRCS website.

8. SAHPRA and NRCS Joint Notice should be published that new import and/or manufacture of respirators with ear loops should be prohibited in the South African market.
    i. Ear loop masks provides impaired protection due to risk of inefficient face seal (required to improve filter efficiency and to force air with any airborne risk to through the respirator and not leaking at side, chin and nose openings).
    ii. NIOSH stipulates in their Non-NIOSH Approved respirator test reports that there are no NIOSH-approved RPE products with ear loops. NIOSH-approved N95 masks have head bands. They furthermore stipulate that limited assessment of ear loop designs indicate difficulty achieving a proper fit.
    iii. A joint SAHPRA and NRCS notice should also be published for already procured/imported respirators with ear loops that have passed SANS 1866-2:2018 testing that while filter efficiency shows how well the filter media performs, **users must ensure proper fit (face seal) is achieved** (see section below relating to '"fit check"). This may be accomplished with the use of clips adapted to enable ear loops to extend behind the head as for head band type RPE.
9. Post Marketing Surveillance" of all Class B respirators: Requirement by SAHPRA on all licensed establishments to conduct post marketing surveillance. Prior to use of respirators purchased, **a minimum of 10 respirators per 1000 (or part thereof) and at least 100 units of 10000 should be randomly picked by the purchaser** from the **boxes in their possession** and sent at a minimum for a Particulate Filter Penetration test at a published accredited South African test laboratory (to sodium chloride) which test must indicate that the respirator has passed the minimum specification. **This cost is borne by the seller (incorporated into cost of sale) and selection of respirators for testing is conducted by the purchaser to maintain integrity of random selection, testing and reporting to the purchaser.**
    a. If respirators pass this test, all respirators in the same production batch may be used, in the same purchase and having been delivered, and in possession of the purchaser.
    b. Failed tests require a second batch of randomly selected (or the same) respirators be sent for formal testing as per point 6.
    c. The final result of the testing must be reported to the supplier and a copy supplied to SAHPRA and the NRCS. The supplier is then required by the regulators to report (as per pharmaceutical batch recalls), on a publicly accessible portal for the particular batch affected (as per many other global regulatory agency standards for quality testing) at a minimum on SAHPRA and NRCS websites (or a link from one to the other).
    d. Publication will only reference the manufacturer, batch failed and test results. The implication should not necessarily be that all respirators from the manufacturer are defective.

e. The seller has to commit to the refund or replacement of the respirators if they do not pass the regulations aligned to the Consumer Protection Act.[18]
    i. The seller will be required to fund destruction of the failed RPE or fund the branding (per respirator) of the product with the corrected SANS specification met by the respirator batch (e.g. SANS 1866-1:2018) to ensure it is not distributed inadvertently to another site and used outside of its tested standard.

10. Export: For any respirators considered for export, points 5 and 6 must be adhered to prior to export and granting of permissions from SAHPRA, NRCS and the DTIC.
11. Publish warnings: A publicly accessible published list on SAHPRA's website must be made available for any RPE that is deemed to be fraudulent in terms of "claims" of product and performance or standards. Furthermore, a list of any batch failures as well as a separate list for repeat failures of batches from a manufacturer and the associated importer, distributor or seller should be published. This is to enable end users and purchasers to check their product against this list and ensure health worker safety.

POLICY: FOR RESPIRATORS ALREADY IN CIRCULATION

(This does not apply to RPE distributed after the date of adoption of processes in this publication as this is catered for in the section for New RPE.)

1. Requirements: Media release and publication of requirements/instructions on how to identify a particulate facepiece respirator Class B device. This is for end users and purchasers and notes the requirement for reporting any poor quality or suspect respirators to SAHPRA.
2. Database Class B Devices – Particulate Respirators: The NRCS establishes and documents a homologation database of respiratory protective equipment as required by the General Safety Regulations under the Occupational Health and Safety Act of 1993 of SAHPRA-registered Class B medical respirators that are considered as meeting the SANS 1866-2:2018, SANS 10338:2009 "Homologation of Respiratory Equipment", SANS 50149:2003 "Respiratory protective devices - Filtering half masks to protect against particles", SANS 50136:1998 "Respiratory Protective Devices - Full Face Masks" and SANS 50143:2003 "Respiratory Protective Devices – Particle Filters" standards to all facilities. This list is partially available as the NRCS register on Homologation Database. SAHPRA will establish a website link to the database to be available on the NRCS website with continued development of this database in perpetuity.
3. Database respiratory equipment: The NRCS establishes, documents, and maintains a homologation database of respiratory equipment as required by the General Safety Regulations under the Occupational Health and Safety Act of 1993. The document should include a list of currently registered manufacturers, importers and distributors of respirator masks and particle filtering half mask respirators intended for use in a non-clinical environment currently registered that may be utilised in a

clinical environment, as well as the specific environment they are suitable for (e.g. not for use in a sterile environment with due care taken to avoid blood spatter (e.g. visor mandatory). SAHPRA will establish a website link to the database to be available on the NRCS website.

4. Public website: A publicly accessible published list on SAHPRA's website must be made available for any RPE that is deemed to be fraudulent in terms of "claims" of product and performance or standards. Furthermore, any batch failure and a separate list for repeat failures of batches from a manufacturer and the associated importer, distributor or seller must be published as a separate list. This is to enable end users and purchasers to check their product against this list and ensure health worker safety.
5. Surveillance: Require post marketing surveillance of all Class B Respirators in circulation that are not listed in 2 and 3 as follows:
    a. Require facilities, purchasers, distributors, juristic entities or any persons that have conducted tests with South African laboratories to submit these results immediately to SAHPRA for collation and assessment.
    b. Require facilities and/or provincial/private distribution points to submit documentation to SAHPRA of any respirators that are not on the published list mentioned in points 2 and 3 to rapidly identify respirators that may be in use that have already failed testing by other parties.
    c. Require that any provincial or private facility with respirators that have not been tested using South African laboratories, are not on the list in Points 2 or 3 and not identified through the process of 5(a), to immediately make available a minimum of 3 (three) respirators of each batch of respirators to the NDOH or provide formal undertaking that the facility will comply with the requirement of testing, quarantine, and replacement of respirators as well as point 5(c)v below where applicable.
        i. Respirators should first be physically inspected for quality including assessment of straps/elastics connected to respirators. Reasonable force should be applied to the straps that simulates application to a health worker. Respirators that are clearly inferior quality or where attachment between securing strap and respirator cannot withstand reasonable force should not be sent for testing but rather quarantined and returned to the supplier for refund.
        ii. The NDOH, with assistance of funders such as the Solidarity Fund, will arrange for courier collection and delivery of respirator samples to South African Laboratories to conduct a Particulate Filter Penetration test at a published accredited South African test facility (to sodium chloride) that meets a minimum of 94% efficiency to 0.3 micron.
        iii. Respirators identified in this section will be **substituted immediately** with identified approved Respirators as in 2 and 3.
        iv. The NDOH/facility will provide formal written feedback of the test results. A passed test will permit use of the acquired respirators to be resumed pending final testing. The respirator batch will then be sent

for formal testing to comply with NRCS, SAHPRA and SANAS regulations and standards with the SAHPRA/NRCS list being updated with final testing results.

v. Failed tests will require continued suspension of use of the respirators with further confirmatory testing as for New Respirators (point 11) as well as formal notification to SAHPRA and the NRCS of interim and final testing results.

vi. Failed RPE will either have to be:

1. Destroyed OR
2. Branded (per respirator) with the SANS specification the respirator meets (e.g. SANS 1866-1:2018 should it meet the standard) to ensure it is not distributed inadvertently to another site and used outside of its tested standard.

Wherever possible the funding must be sought from the supplier of the goods and the supplier should be held accountable to the full extent of the law. Confirmation of destruction or rebranding will be obligatory to SAHPRA and the NRCS.

Testing in this section should be undertaken with urgency with the process concluded within 10 business days. As identified stock is expected to be removed from use, delays may translate into inadequate respirators available for patient care.

6. New RPE Purchases: All purchases of new respirators will be required to meet the standard set out in under "For New RPE".

RESPIRATORS CONTEMPLATED FOR EXTENDED USE OF PARTICULATE RESPIRATORS

The CDC and World Health Organisation (WHO) agree that disposable RPE, like N95, KN95 or FFP2 respirators, are not approved for routine decontamination as conventional standards of care.

WHO has suggested the possibility of single-use RPE extended use by the same individual for up to 6 hours.

The US CDC has published guidance and guidelines in optimizing Supply of PPE and Other Equipment during shortages available at:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Fhealthcare-supply-ppe-index.html

Since risks are associated with these measures, special criteria and precautions should be used when adopting them, confining their use to situations where they are indispensable.

Policy: Extended Use of Particulate Respirators

SAHPRA supports the extended use of single use RPE

- **up to a maximum of 6 hours for quality approved respirators (as per this document) or;**
- **as specified by the individual manufacturer of the distributed particulate respirator, but to a maximum of 8 hours total use**

when supply optimisation is required or shortages are experienced.

Extended use may only be considered in constrained environments.

- Facilities are responsible to clearly communicate the risks of extended use to health workers in the facilities in which extended use policies are implemented. This must include techniques for donning and doffing if respirators are reapplied.
- It remains preferable for extended use to be undertaken without interval donning and doffing.
- Facilities should familiarise themselves with both the CDC and WHO-PAHO documents regarding extended use and ensure formal policies are published to health workers in the facility with OHS training.

ALL RESPIRATORS ISSUED TO HEALTH WORKERS

Owing to the vast array of respirators now in circulation and entering the healthcare space, and aligned to international and local best practice, requirements for all respirators issued to health workers are as follows:

- All facilities that issue particulate respirators of any type to health workers are responsible to ensure the health worker is formally **fit tested** either quantitatively, qualitatively, or both by a person certified and qualified to do so (refer below).
- Fit testing is applicable to an individual and to a **specific respirator brand and size**. Fit testing is required whenever either of these is changed or the individual's facial features have altered (weight gain or loss more than 10kg, facial injury etc.)
- Health workers should be formally trained to conduct **fit (seal) checks** when donning respirators using positive and negative pressure checks. Areas should be available for health workers who wish to conduct a fit check using a challenge agent.
- All facilities must keep a register of fit testing for each health worker for each respirator type and size the health worker uses.
- Fit testing is compulsory at least once every 12 months for an individual health worker.
- **Valved respirators should not be used in clinical practice during COVID19**.[9] The vast majority of valved respirators do not have exhalation valve filters. The absence of exhalation filtration places patients or other healthcare workers at risk from contracting COVID19 or other infectious disease such as TB from the person wearing the respirator. Some elastomeric half face reusable respirators specifically also have exhalation valves. Use of valved devices should only be considered when quality respirators are no longer accessible or the NDOH or regulators pronounce a critical shortage of respirators.
- **Fit Testing and Checking facility procedures and protocols should be developed in collaboration with the National Institute for Occupational Health (NIOH) with further information available at** https://www.nioh.ac.za/specialised-services/respirator-fit-testing/

Minimum guidelines for Fit Testing and Checking is as follows:

Fit Testing and Checking

Fit testing forms a vital and indispensable part of achieving the objective filtration of virus and bacteria in protecting health workers and patients. Without individual fit testing for each respirator brand and size and per individual, the impact of ensuring quality respirator supply in the market is severely limited.

a) Quantitative & Qualitative

Fit testing should be carried out at least once annually for every health worker who is required to wear a particulate respirator per specific respirator brand and size.

Quantitative fit testing is defined in ANSI Z88.2-1992 as: "A fit test that uses an instrument to measure the challenge agent inside and outside the respirator." This procedure is more precise than the qualitative fit test. It is also performed less commonly because of its complexity. Access to quantitative fit testing and the cost of the required analyzation instrument may be challenging and prohibitive.

Qualitative fit testing is defined in ANSI Z88.2-1992 as, "A pass/fail test that relies on the subject's response to detect the challenge agent." Because this test relies upon the subjective response of the individual being tested, the reproducibility and accuracy may vary. The qualitative test is more commonly performed because of its simplicity. The necessary testing equipment is also easier to obtain and more economical than quantitative testing equipment.

The three accepted test methods for qualitative fit testing all follow essentially the same format and dictate the type of air-purifying element that is used:

- **isoamyl acetate** (more commonly known as banana oil) requires respirators equipped with organic vapor cartridges;
- **saccharin solution aerosol** requires respirators equipped with **particulate filters;**
- **irritant fume** is used for applications requiring high-efficiency or HEPA filters.

b) Frequency

Part 9.1.4 of ANSI Z88.2-1992 states that "A respirator fit (seal) test shall be carried out for each wearer of a tight-fitting respirator at least every 12 months." In addition, fit testing is generally recommended immediately if the subject experiences a weight change of 10kg or more, has significant dental changes, or has reconstructive surgery or a facial disfigurement (scarring). All of these instances could affect the facepiece seal.

c) Fit Checks

Fit testing should not be confused with a respirator fit check. ANSI Z88.2-1992 defines a fit check as, "A test conducted by the wearer to determine if the respirator is properly sealed to the face." It is recommended that a fit check be performed each time the respirator is donned or adjusted. The fit check is a quick method to determine if the respirator is properly sealed to the face.

Under part A.6 of ANSI Z88.2-1992, procedures for conducting a fit check are described. The two most commonly performed methods are the positive- and negative-pressure tests. The positive-pressure check requires the wearer to cover the exhalation valve (if present - in the case of elastomeric filtered respirators suggested in times of extremely constrained supply) of the tight-fitting respirator (placing the palm over the valve is usually sufficient) and exhale. If there is no indication of air escaping, the fit is considered satisfactory. The wearer then inhales. If no leakage is detected, the facepiece seal is satisfactory. For valved masks during a negative pressure fit check, the inlet opening of the respirator's cartridges or filters are covered prior to inhalation.

Fit checking requires exposing the wearer to a challenge agent (isoamyl acetate, saccharin mist, irritant fume). If the wearer does not detect the challenge agent, the fit check is successful. This method is the only way respirators without valves can be effectively tested.

It is important to note that a fit check is **NOT** a substitute for a quantitative or qualitative fit test. Fit tests follow detailed, step-by-step guidelines; fit checks do not.

Respirator Reuse or Reprocessing and Reuse

Respirators contemplated for reuse or reprocessing (decontamination) and reuse of Particulate Respirators:

As at the date of this policy, SAHPRA regulations do not enable (and therefore prohibit) reuse, or reprocessing and reuse of disposable single use RPE.

Policy: Respirator Reuse or Reprocessing and Reuse

Until such time as SAHPRA and the NDOH determine and publish notice of an extreme dire RPE shortage or national inability to meet RPE demand, reprocessing and reuse in any facility is not permitted.

Conclusion

This policy enables structures and systems to ensure the quality for new respirators to be supplied and for respirators already in circulation to be certified as sage. This document also addresses potential extended use, reuse and reprocessing of respirators. It is intended to safeguard our national healthcare assets and the ability for our patient population to receive quality and safe care.

This formal structure will incentivise suppliers, purchasers and facilities to ensure appropriate quality products are supplied. It will limit illness contracted by healthcare workers. This solution ensures that, irrespective of purchase and supply processes (central or provincial, public or private), the quality of RPE supplied to health workers will be the best quality to maintain safe and quality care to patients in South Africa, and possibly the broader continent.

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21. CDC Guidance: "Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators"

ANNEXURE 1: ACRONYMS

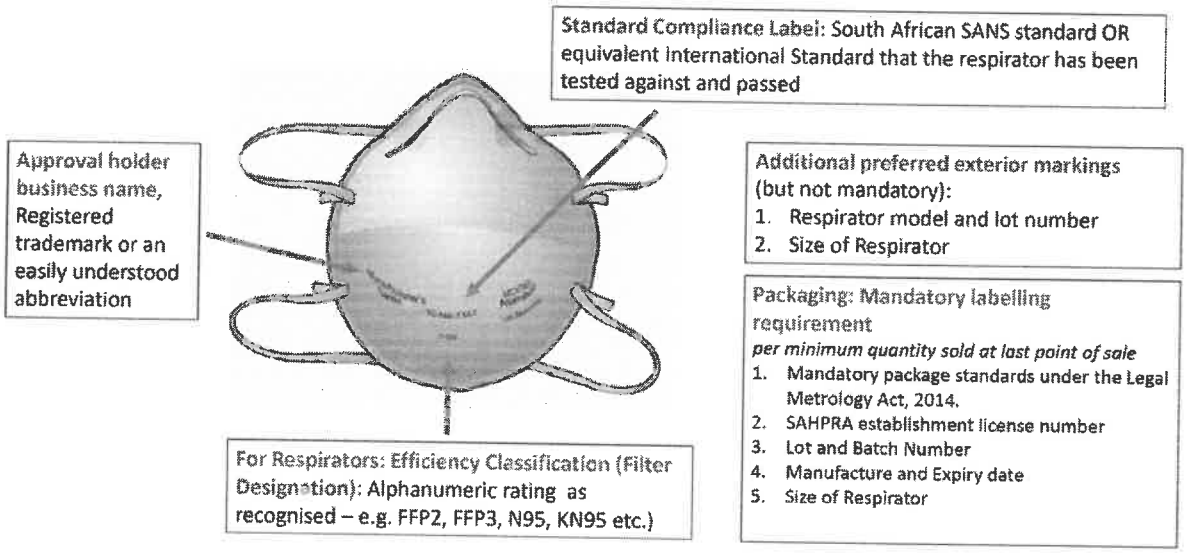
ACHIGH	American Conference of Governmental Industrial Hygienists
AGP	Aerosol Generating Procedures
ANSI	American National Standards Institute
B4SA	Business for South Africa
CDC	Centres for Disease Control American British Safety Industry Federation
COVID-19	Corona Virus Disease 2019
DTIC	Department of Trade, Industry and Competition
FFR	Filtering Facepiece Respirator
NDOH	National Department of Health
NICD	National Institute for Communicable Diseases
NIOH	National Institute for Occupational Health (South Africa)
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
NRCS	National Regulator for Compulsory Specifications
OHS	Occupational Health and Safety
OSHA	Occupational Safety and Health Administration
PFP	Particulate Filter Penetration
PPE	Personal Protective Equipment
PFMAA	Public Finance Management Amendment Act
PPPFA	Preferential Procurement Policy Framework Act
RPE	Respirator Protective Equipment
SABS	South African Bureau of Standards
SAHPRA	South African Health Products Regulatory Authority
SANS	South African National Standards
STP	Standard Test Procedure
TB	Tuberculosis
WHO	World Health Organisation

ANNEXURE 2: SUMMARY OF RESPIRATORY PROTECTIVE EQUIPMENT

	Cloth mask	Non-Sterile Medical (Surgical) Mask	Non-Sterile Medical (Surgical) Mask	Sterile Medical (Surgical) Mask	Dust Mask	Respirator Mask	Respirator Mask (Particle Filtering Half Mask
							
Examples		1-ply, 2-ply or 3-ply masks	3-ply masks	3-ply masks		N95, KN95 **FFP2 or better**	N95, KN95 **FFP2 or better**
Classification	Non-medical General	Non-medical General	Class A medical device	Class A medical device (Sterile)	Non-medical General	Class B medical device	Non-medical e.g. mining industry
SAHPRA manufacturer, distributor, wholesaler licence	No	No	No Exemption from licensing requirement for non-sterile Class A medical devices	Yes	No	Yes	No
NRCS sales permit/ authorisation (LOA)	No	No	No	No	No	Yes	Yes
Specification/ Standards/ Other Legislation	None Department of Health guideline on the 'Use of Cloth Face-Masks by Members of the General Public in South Africa during the COVID-19 Pandemic'	None	Yes SANS 1866-1 :2018 Legal Metrology Act,2014 (Act 09 of 2014) in terms of packaging and labelling	Yes SANS 1866-1 :2018 Legal Metrology Act,2014 (Act 09 of 2014), in terms of packaging and labelling.	None	Yes SANS 1866-2 2018 SANS 50149:2003 VC8072:2011 - Compulsory Specification for respiratory protective devices	Yes. SANS 1866-2 2018 SANS 50149:2003 VC8072:2011 - Compulsory Specification for respiratory protective devices
Intended use and purpose	Non-medical environment Respiratory hygiene and extension of coughing and sneezing etiquette	Non- medical environment Respiratory hygiene and extension of coughing and sneezing etiquette Capturing large particles or droplets from the wearer and preventing them from being spread to their environment	Clinical/ Healthcare environment Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Clinical/ Healthcare environment Fluid resistant and provides the wearer protection against large-particle droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Non-medical and Non-hazardous environments One way protection only capturing large particles or droplets from the wearer and preventing them from being spread to their environment	Clinical/ Healthcare environment Reduces wearer's exposure to particles including small particle aerosols and large droplets Protects the patient from the wearer's respiratory emissions.	Non-medical environment Hazardous environment Reduces wearer's exposure to particles including small particle aerosols and large droplets
Face seal fit	Loose-fitting	Loose-fitting	Loose-fitting	Loose-fitting	Loose-fitting	Tight-fitting	Tight-fitting
Filtration	None	None	Does **NOT** provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Does **NOT** provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	None	Filters out at least 94% of airborne particles including large and small particles	Filters out at least 94% of airborne particles including large and small particles
Use limitations	Wash and iron after each use Discard when mask is worn out or damaged	Single-use only Disposable	Single-use only Disposable Discard after each patient encounter	Single-use only Disposable Discard after each patient encounter.	Disposable	Single use only Disposable Discard after each patient encounter	Disposable Discard when mask is damaged or deformed; or breathing becomes difficult

ANNEXURE 3: METROLOGY: SAHPRA CLASS B RESPIRATORS

Exterior Marking requirements: SAHPRA Class A Masks and Class B Respirators



The position of markings indicated are not prescriptive but rather provide an example of markings required on Medical Face Masks and Filtering Facepiece Respirators.

ANNEXURE 4: RESPIRATORY PROTECTIVE EQUIPMENT REPROCESSING AND REUSE

The following information is provided for in the event a dire shortage or stock-out of RPE is notified by SAHPRA and the NDOH.

- **This is provided in an effort to enable the healthcare sector to understand requirements and regulation that will be in place should dire shortage or stock-outs be experienced.**
- **This information and formal policy will be updated and published as necessary and if required.**

RPE decontamination and reuse may be needed during times of extreme shortage to ensure continued availability.

During shortages of approved and compliant RPE as per national and international legislative requirements, stopgap measures for optimising their use may be considered, among them extended use and reuse.

Extended use is recommended over reuse, because the latter requires a controlled procedure in the health services and implies that the staff performing it will come into contact with contaminated respirators, increasing the risk of occupational exposure.

It is recommended that the distribution and use of reusable air purification respirators/half masks/elastomeric respirators compliant with the regulatory National SANS standards is preferred over reprocessing and reuse of RPE intended for single use (https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html).

During critical respirator shortages, reprocessing can be considered. Although saturated steam, UVC radiation, and gas plasma or vaporized hydrogen peroxide sterilization are the respirator reprocessing methods with the most evidence of efficacy to date, no method can be adopted without prior local validation testing in the health facility.

A written protocol for the procedure should be also prepared and health workers trained in the proper use of the reprocessed respirators. Respirator reprocessing should be regulated by the regulatory authority with jurisdiction over these medical devices.

The method selected by a health facility will depend on its infrastructure and ability to prepare and implement operating protocols that guarantee the efficacy and safety of the respirators after reprocessing.

As such the NDOH and SAHPRA align with the WHO/Pan American Health Organisation (PAHO) policy document "Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages 10 June 2020"[17] as well as CDC guidance "Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators"[18].

Prior to any facility (public or private) considering reuse and/ or decontamination, the following is required:

1. Recommendations on rational use and considerations on decision making of respirators should be followed as per WHO guidance[17].
2. Extended use is considered the first option in constrained environments with risks clearly communicated to healthcare workers in the facilities in which extended use policies are implemented. This is preferred over reuse.
3. Precautions for respirator reuse must be adopted for any respirators contemplated for reuse, and well communicated to Healthcare workers in the facility.
4. Risks associated with reuse including loss of fit, loss of filtration efficiency and risk of spreading infection must be communicated as well as strategies to ensure healthcare workers are enabled to identify and prevent same.
5. Since there are no standardized and consolidated respirator reprocessing methods, this possibility should be considered only during critical shortages or the absence of respirators.
6. Facilities are required to apply for license to SAHPRA to perform reprocessing in the facility.
    a. Local validation testing in accordance with 1 through 5 is required prior to any reuse of respirators post reprocessing to ensure shape and fit of respirator are preserved and to determine the maximum number of reprocessing cycles.
    b. Facilities are required to provide evidence that critical shortage or absence of respirators exists and that new respirators are unlikely to be available in sufficient numbers.
    c. A written protocol for the process is required per facility including guarantee that health workers will be trained in the proper use of reprocessed respirators.
    d. Minimum information to be provided to SAHPRA includes:
        i. A description of the reprocessing process, including the scientific rationale
        ii. Microbial testing that validates the reduction/disinfection of the pathogen burden
        iii. A description of the chain of custody and safeguards to prevent inadvertent exposure
        iv. Compatibility of the respirator material with the reprocessing process
        v. Performance testing, including filtration performance, fit test data (airflow resistance, and fluid resistance)
        vi. Adequate labelling of the reprocessed device that includes the maximum total duration and the number of times the device can be reprocessed, and the method for tracking the duration and number of times it has been reprocessed.
7. Reprocessing may only be undertaken under the following framework:

a. Only respirators that are SAHPRA accredited Class B devices and batch tested as compliant in terms of the testing parameters for new and existing respirators may be contemplated for reprocessing.
b. Any respirator contemplated for reprocessing must be decontaminated and subjected to complete testing as per point 6. for new respirators for the first 20 respirators subjected to reprocessing.
c. This is specific to each respirator manufacturer type and per batch purchased.
d. This testing is required to be performed for each number of cycles that the specific manufacturer respirator undergoes in terms of reprocessing (e.g. 20 respirators tested per number of reprocessing cycles. Approval is only supplied per brand and per batch tested for the number of cycles.
e. On-site fit testing must be available should a health worker be concerned that fit post reprocessing is compromised.
f. Testing must confirm the following with respect to all respirators tested:
i. Efficacy of respirator disinfection/sterilisation
ii. Maintenance of respirator filtration efficiency must be greater than or equal to 94% efficiency to 0.3 microns
iii. Retention of respirators shape and therefore its fit, as well as the integrity of securing straps
iv. Safety of the respirator's user (e.g. toxicity after reprocessing). Test results should be cross referenced with CDC "Decontamination Assessment results" available at https://www.cdc.gov/niosh/npptl/respirators/testing/DeconResults.html

8. The following advice must be available to all health workers contemplating reuse of reprocessed respirators:
    a. Current evidence on the efficacy of the methods for decontaminating a respirator specifically against SARS-CoV-2 is still limited and constantly evolving. It should also be borne in mind that other pathogens may be present in reprocessed respirators; health workers should therefore handle reprocessed respirators with extreme caution.
    b. Health workers should take the following precautions when using a reprocessed respirator:
        i. Avoid touching the inside of the respirator, and clean hands with soap and water or alcohol-based hand sanitizer before and after touching the respirator.
        ii. Visually inspect the respirator to determine whether its integrity has been compromised.
        iii. Check that the straps, nose bridge, and nose foam material are not degraded, as this can affect the quality of the fit and seal.
        iv. Perform a seal check immediately after donning each respirator, and do not use a respirator without an adequate seal.
        v. If the integrity of any part of the respirator is compromised, or if a successful user seal check cannot be performed, discard the respirator.

ANNEXURE 5: NOTE FROM THE DEPARTMENT OF TRADE INDUSTRY & COMPETITION (DTIC)

"I call on every South African to remain strong and steadfast in these most difficult times. Stay safe and protect South Africa." [1]

President Matamela Cyril Ramaphosa, 01 August 2020

In the procurement of medical products for the Republic of South Africa and in response to Covid-19, the South African Specifications referenced in this document must be adhered to. The international standards made reference to in this document serve to assist and guide in referencing such foreign specifications.

In addition to adherence to latest medical research and best practices, it must be requested that in the procurement of medical products the Republic of South Africa's Re-imagined Industrial Strategy[2], Industrial Policy[3] and Procurement Legislation be given attention.

The central tenant of our Republic's re-imagined industrial strategy and policy is to address our triple challenges of poverty, inequality and unemployment. Within this context it is imperative that the procurement of medical products in response to Covid-19 (and in-general) should seek to support local manufacturers – the procurement (demand) of local manufactured goods/products (supply) has a net-positive impact on our country's socio-economic realties.

Within this context our Republic has enacted Legislation and Regulations that impose strict duties on public sector procurement: The Preferential Procurement Policy Framework Act 05 of 2000[4] (PPPFA) and the PPPFA Preferential Procurement Regulations[5] , which came into effect on the 07 December 2011 empower the Department of Trade, Industry, and Competition (the DTIC) to designate industries, sectors and sub-sectors for local production at a specified level of local content.

It must be noted that regulation 8(2) of the Preferential Procurement Regulations requires that organs of state to include local content in the invitation of bids and tenders. Regulation 8(5) states that if bids fail to meet the required local content such an application should not be acceptable. Further, local content rules require organs of state to populate Standard Bidding Documents 6. 2 (SBD 6.2) with a list of designated products and to circulate local content annexures.

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[1] http://www.thepresidency.gov.za/speeches/statement-president-ramaphosa-progress-national-coronavirus-response

[2] http://www.thedtic.gov.za/wp-content/uploads/Re-imagining-Industrial-Strategy-FINAL-13-June-2019.pdf

[3] http://www.thedtic.gov.za/wp-content/uploads/publication-IPAP.pdf

[4] http://www.treasury.gov.za/divisions/ocpo/sc/PPPFA/Preferential%20Procurement%20Policy%20Framework%20Act,%202000%20(Act%20No.5%20of%202000).pdf

[5] [5] http://www.treasury.gov.za/divisions/ocpo/sc/PPPFA/1-34350%208-6%20NatTreas.pdf

Local content is applicable on goods designated for local production regardless on the procurement methods used by an organ of state. It is also applicable on turnkey projects where public money is spent and the project owned by the government.

The Designated Local Content information can be found here:
http://www.thedtic.gov.za/sectors-and-services-2/industrial-development/industrial-procurement/

The DTIC remains the custodian of the Designated Local Content legislation. The DTIC may and can request all public entities to supply procurement information, especially information pertaining to adherence to local content legislation. Moreover, attention must also be given to the Judgement of 20 July 2020 in the High Court of South Africa, Gauteng Division Pretoria by Judge P. D. Phahlane in regard to Designated Local Content and procurement by organs of state. Judge Phahlane noted in the judgement that the DTIC has discretionary power and is enabled by the PPPFA in enforcing policies of our government, particularly when ensuring procurement from local manufacturers using local materials within the Republic of South Africa.

ANNEXURE 6: PARTICULATE RESPIRATORS: DTIC PROCUREMENT ADVISORY FOR PROCUREMENT OFFICERS

PROCUREMENT OF PARTICULATE RESPIRATORS (FFP2, FFP3, N95 OR KN95) USED IN A CLINICAL ENVIRONMENT FOR THE PUBLIC SECTOR (NATIONAL, PROVINCIAL AND LOCAL MUNICIPALITIES)	
Attention and reference are directed to the Preferential Procurement Policy Framework Act 5 of 2000 ("PPPFA") with specific reference to Regulation 8 (Local production and Content) of the regulations gazetted 20 January 2017. Respirators (and the majority of PPE) are listed under "Clothing and Textiles" as a "Designated product" for 100% local production and procurement. This means that all procurement of particulate respirators is subject to the 100% local content requirements.	
1.	**Specification:**
	Description: Particulate filtration respirators used for protection against airborne diseases such as tuberculosis. FFP2 or N95 or KN95 respirator, or higher Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cup shaped) • A particulate filtration half mask must cover the chin, mouth and nose; **it must not have an exhalation valve** • The particulate filtration respirator must not disintegrate during continuous or intermittent use in a 8 hour work day • Parts of the particulate filtration respirator that are more likely to come into contact with the wearer must be hypo-allergenic • Filter performance must meet standards relevant to the specific respirator classification • The respirator must have an adjustable/self-adjustable head harness which ensures ease of donning or removal of the respirator; **respirators with ear loops are prohibited** • The particulate filtration respirator must have a filtration efficiency of at least 94% for FFP2 respirators and 95% for N95 and KN95 respirators • The particulate filtration respirator shall have the equivalent of an external hydrophobic fabric layer for droplet protection • Specific lot and brand testing is mandatory - cost will be borne by the seller Labelling Requirements: 1. Name or trademark 2. Filter efficiency/Classification 3. Approval number 4. Standard compliance 5. Size of the respirator
2.	**Local Content: 100%**
	If a raw material or input to be used in the manufacturing of the particulate respirators is not available locally, bidders should apply for written authorisation/exemption from **the DTIC** should there be a need to import such raw materials or input. Authorisation/Exemption letters are granted on a case by case basis and are tender specific. A copy of the authorisation letter must be submitted together with the bid documents at the closing date and time of the bid. For further information, bidders may contact the DTIC -

	localcontent@thedtic.gov.za **Note: N95 and KN95 particulate respirators are not produced within the borders of South Africa; any bidder supplying these particulate respirators must obtain a letter of authorisation from the DTIC prior to the closing date and time of the bid.**
3.	**Compliance Requirements**
	• Quality certificate - SANS 1866-2:2018 with inward leakage test and/or SANS 50149:2003 • Homologation Certificate from the National Regulator for Compulsory Specifications (NRCS) • Company must be registered with South African Health Products Regulatory Authority (SAHPRA) as a medical device establishment as well as compliance with **Class B** medical device regulations **Certificates must be submitted with the bid documents**.
4.	**Quality Assurance**
	Prior to use of respirators purchased, a minimum of 10 respirators per 1000 (or part thereof) and at least 100 units of 10000 should be randomly picked by the purchaser of the boxes in their possession and sent at a minimum for a Particulate Filter Penetration test at a published accredited South African test facility (to sodium chloride) which test must indicate that the respirator has passed the minimum specification. This cost is borne by the seller (incorporated into cost of sale) and test conducted by the purchaser to maintain integrity of random selection, testing and reporting to the purchaser. The seller has to commit to the refund or replace the respirators if the respirators don't pass; aligned to the Consumer Protection Act.