

A STRATEGY TOWARDS APPROPRIATE PROCUREMENT OF DISPOSABLE PERSONAL RESPIRATORY PROTECTIVE DEVICES

Purpose

This document is drafted to present a position regarding the specification and procurement of disposable particulate filtering half masks for use in healthcare as respiratory protection against the airborne transmission of tuberculosis (TB). It primarily aims to describe a technically sound policy for specification and accreditation of suitable respirators. This document does not consider operational issues surrounding correct and safe respirator use. This document does not propose to affect the application of good procurement practice, planning and finance management.

Existing Standards

A national standard for respirators has been published and is readily available in **SANS 50149:2003 ‘Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing and marking’**. This document should not be read to amend or oppose the SANS 50149 in any way. The SANS 50149:2003 is an identical implementation of the EN149:2001 Ed2.

While the national standard is an identical implementation of the EN149:2001, the US NIOSH approved 42 CFR 84 standard continues to be incorrectly referenced as the primary criteria of certification in South Africa.

The SANS 50149:2003 standard is considered by the CSIR to be a technically superior standard and any device without the SANS 50149 or EN 149 mark cannot be declared to be SANS compliant.

The benefit of considering the EN 149 (latest edition) standard is its inclusion of the criteria for total inward leakage, including fit and seal, in addition to the most penetrating performance of the filter media.

NIOH has established and maintains an online registry where NIOSH approved models of respirators are listed. For a review of approved N95 respirators the website http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/n95list1.html can be viewed (visited 16 April 2015). No national registry is currently available for SANS 50149 compliant devices.

Technical Overview

A particle filtering half mask covers the chin, mouth and nose. This is distinct from a full face mask. A half mask consists substantially of filter material which forms an inseparable part of the device. The mask may include exhalation valves which aid comfort.

Three classes of device are available, namely FFP1, FFP2 and FFP3. FFP2 and FFP3 devices include the protection of the lower class devices.

FFP2 devices are recommended for use as medical respiratory protection.

Technical Recommendations for medical respiratory protection

Markings:

Devices shall be designated in accordance with the requirements of the SANS50149 as follows:

Specification	Year of publication	Class
Particle filtering half mask SANS/EN 149	(2001)	FFP2

Devices shall also include a trademark identifying the manufacturer. Components with a significant bearing on safety shall be identified.

Packaging shall be designated in accordance with the requirements of the SANS50149 with the following:

- Name or trademark
- Type identification marking (particle filtering half mask)
- Classification (FFP2)
- Identification of the standard of compliance
- Year of end of shelf life
- Recommended conditions of storage

Packaging:

Particle filtering half masks shall be packaged such that they are protected from mechanical damage or contamination during transit, storage and unpacking.

The packaging shall contain the manufacturer's information regarding appropriate donning and doffing of the devices.

Materials:

The materials of construction shall be suitable to withstand 12 hours of intended use.

The particle filtering half masks shall not release materials to the air or user during use.

Self-adjusting head harness:

The self-adjusting head harness shall be durable enough to survive repeated donning and doffing during a 12 hour work day.

Sizing:

Sizing shall be available in small, medium and large with bulk orders reflecting a normal distribution across these sizes.

A distribution of **20% SMALL**, **60% MEDIUM** and **20% LARGE** is recommended but local demographics must be accommodated when placing orders.

National registry of SANS 50149 compliant particle filtering half masks

It is recommended that a national registry be established identifying and listing particle filtering half masks that comply with the requirements of SANS 50149. Such a registry should be established and maintained under the direction of the NIOH.

Acceptance of 42 CFR 84 certified devices.

As the national standard SANS 50149:2003 has been available for a considerable period of time an extended grace period for compliance is not considered necessary. The CSIR considers the major suppliers of particle filtering half masks to have products which comply with 42 CFR 84 in addition to the EN149 and thereby SANS 50149. The industry should therefore not be materially affected by a shortage of compliant devices. The timely invoking of a historically adopted national and international standard, for the purposes of improved safety and compliance, should not be considered a barrier to trade.