

Regulation of chemical disinfectants and respiratory protective equipment

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2020

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Compulsory Specification for chemical
disinfectants (herein referred to as VC8054:2017)
as published by Government Notice No. 1119
(Government Gazette No. 41186) of 20 October
2017

SCOPE

- Chemical disinfectants used for **disinfection purposes** on **inanimate surfaces** in all areas of application.
- Definition for chemical disinfectant: 3.1.3 & 3.1.4 of SANS 54885.
- 3.8 of VC8054:2017: Any chemical substance making any **public health claim** (defined 2.2.11 of VC8054:2017) shall comply with compulsory specification (VC).
- Excluded:
 - Antiseptics (defined in 3.1.1 & 3.1.2 of SANS 54885);
 - Chemical disinfectants exclusively for use in veterinary areas (1.2 of VC8054:2017 & 1 of SANS 54885);
 - Treated articles and substances (1.3, 2.2.19 & 3.9 of VC8054:2017).

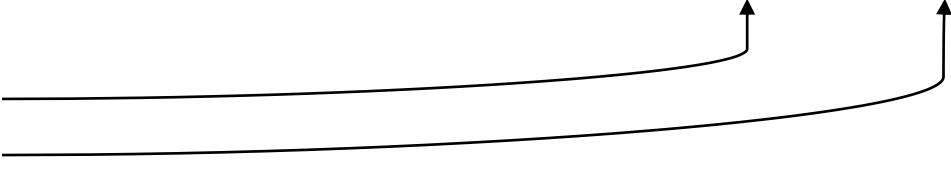
TRANSITIONAL PROVISIONS

- VC8054:2017 became effective on 20/10/2019.
- Formulations already registered pursuant to VC8054:1999:
 - Holder of registration shall submit proof of compliance with VC8054:2017 by means of application for modification or extension of registration before 20/10/2020;
 - NRCS form No. CMM FM 8054-4;
 - Information of manufacturing plants and warehouses;
 - SDS satisfying requirements of SANS 11014;
 - Bill of materials of packaging material;
 - New product label;
 - Test reports;
 - Where relevant, evidence of QMS certification;
 - Where relevant, evidence of product certification;
 - Where relevant, quality manual;
 - Where relevant, COP and routine test evidence.
 - Holder of registration shall ensure and proof compliance with new requirements by means of application for modification or extension of registration within 2 years from effective date of new edition of referenced standard.

REGISTRATION OF CHEMICAL DISINFECTANTS

- Requirement of 3.4 of VC8054:2017.
- Registration granted per chemical disinfectant formulation per manufacturer or importer.
- Chemical disinfectant formulation defined in 2.2.5 of VC8054:2017.

NEW REGISTRATION NUMBER

- Arrangement of registration number:
 - **NRCS Registration: NRCS/8054/000000/001.**
 - Customer number 
 - Sequential number
- 3.5 of VC8054:2017: Shall be legibly and indelibly marked on packaging.
- Formulations already registered pursuant to VC8054:1999: Will get new registration number when issued with extension of registration.

ADDITIONAL REQUIREMENTS ENFORCED DURING SURVEILLANCE INSPECTIONS

- 4 of VC8054:2017:
 - Packaging requirements;
 - Non-conformance: Breakages of containers, leakages and spills during handling, transportation and storage.
- 6.1 of VC8054:2017:
 - Production (manufacturing and packaging) operations shall comply with clause 7 of SANS 22716.

GENERAL PROVISIONS & EQUIVALENCE OF STANDARDS

- 7 of VC8054:2017: General provisions
 - Reference to specific micro-organisms on product label or any related marketing materials shall be only for those tested;
 - No person shall advertise a chemical disinfectant in any manner, which contains any information, claim, reference or declaration not permitted on the label in accordance with VC8054:2017;
 - Chemical disinfectants shall not contain, as part of their composition, any chemical substances that are banned/ restricted by any SA legislation and /or international agreements that SA has ratified.
- 8 of VC8054:2017: Equivalence of standards
 - Test results against other standards only acceptable if proven in the form of a declaration report from an accredited CAB to be technically equivalent to the relevant SANS;
 - Applicant responsible for obtaining such a declaration report.

VC 8072:2011

VC 8072 COMPULSORY SPECIFICATION FOR RESPIRATORY PROTECTIVE DEVICES Published by Government Notice No.34272 of 13 MAY 2011



1 SCOPE

- 1.1 This Compulsory Specification applies to respiratory protective devices, hereinafter referred to as "RPD's".
- 1.2 The following classes of RPD's are excluded from this Compulsory Specification:
 - 1.2.1 Body-worn escape type breathing apparatus as covered by the scope of SANS 1737.
 - 1.2.2 RPD's designed and manufactured specifically for use by the armed forces or the maintenance of law and order.
 - 1.2.3 RPD's intended for use in diving applications.
 - 1.2.4 Surgical face masks as covered by the scope of SANS 1866. (SANS1866 was reviewed in 2018 and SANS1866-2:2018 Respirators now have to comply to SANS 50149 as part of their performance requirements)

VC 8072:2011 DEFINITIONS

2.1 For the purposes of this Compulsory Specification the definitions in SANS 50132: *'Respiratory protective devices - Definitions of terms and pictograms'*, the classification given in SANS 50133: *'Respiratory protective devices - Classification'* and the nomenclature given in SANS 50134: *'Respiratory protective devices - Nomenclature of components'* shall apply.

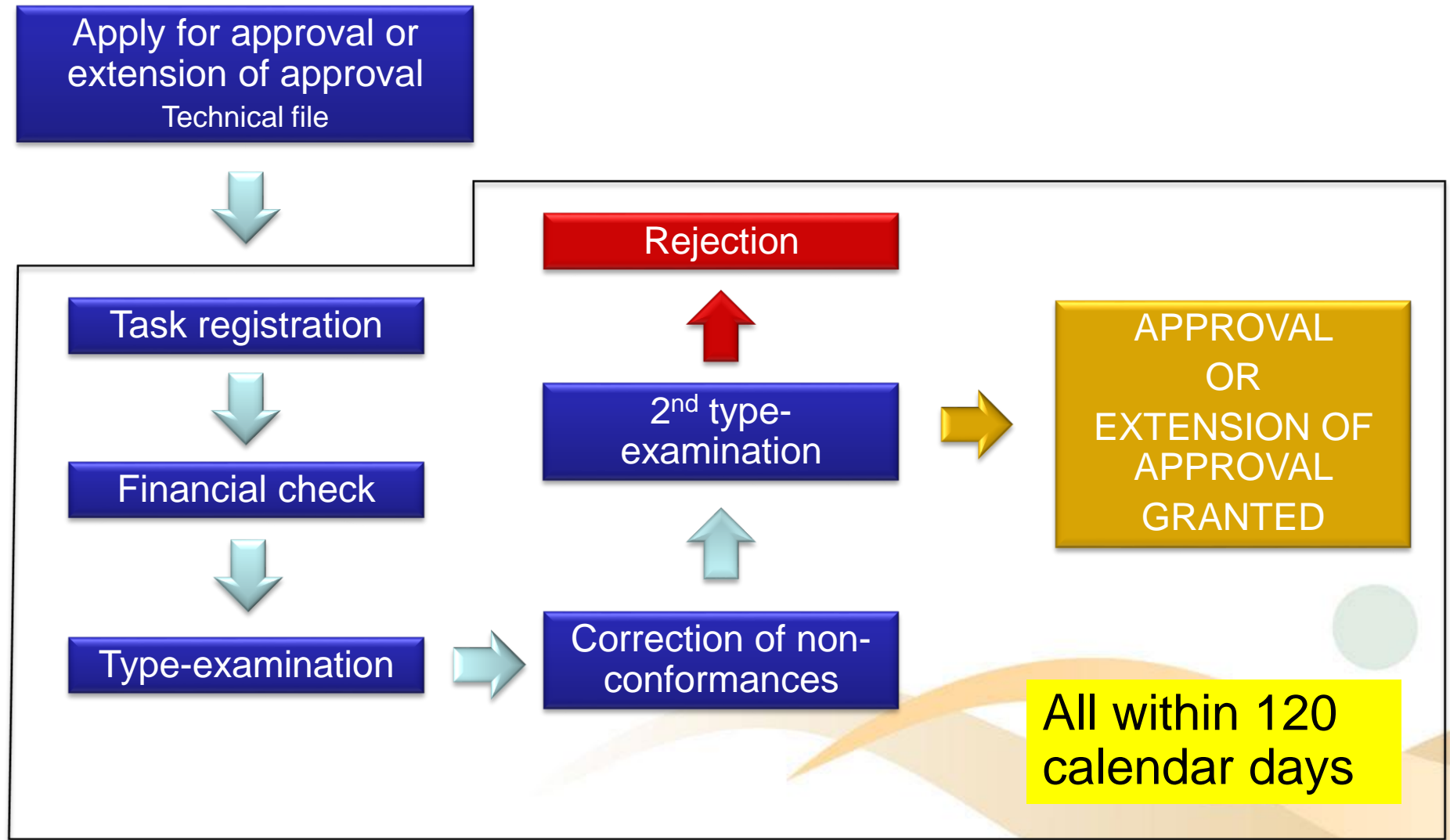
Specific Requirements (relevant for COVID-19)

- **Full-face masks shall comply with SANS 50136**
- **Half masks and quarter masks shall comply with SANS 50140**
- **Mouthpiece assemblies shall comply with SANS 50142**
- **Particle filters shall comply with SANS 50143**
- **Filtering half masks for protection against particles shall comply with SANS 50149**

Administrative Requirements

- **The manufacturer or importer shall apply to the NRCS for approval of every type and model of respiratory protective device in accordance with the requirements of Annex A of VC8072:2011**
- **A RPD type shall be approved by NRCS before it is imported or offered for sale.**
- **The manufacturer and/or importer shall inform the NRCS of any change in design or components affecting any mandatory requirement of this compulsory specification.**
- **Should a**

APPROVAL PROCESS (Registration/Homologation/LOA)



Administrative Requirements

Effect of declaration as compulsory specification 25

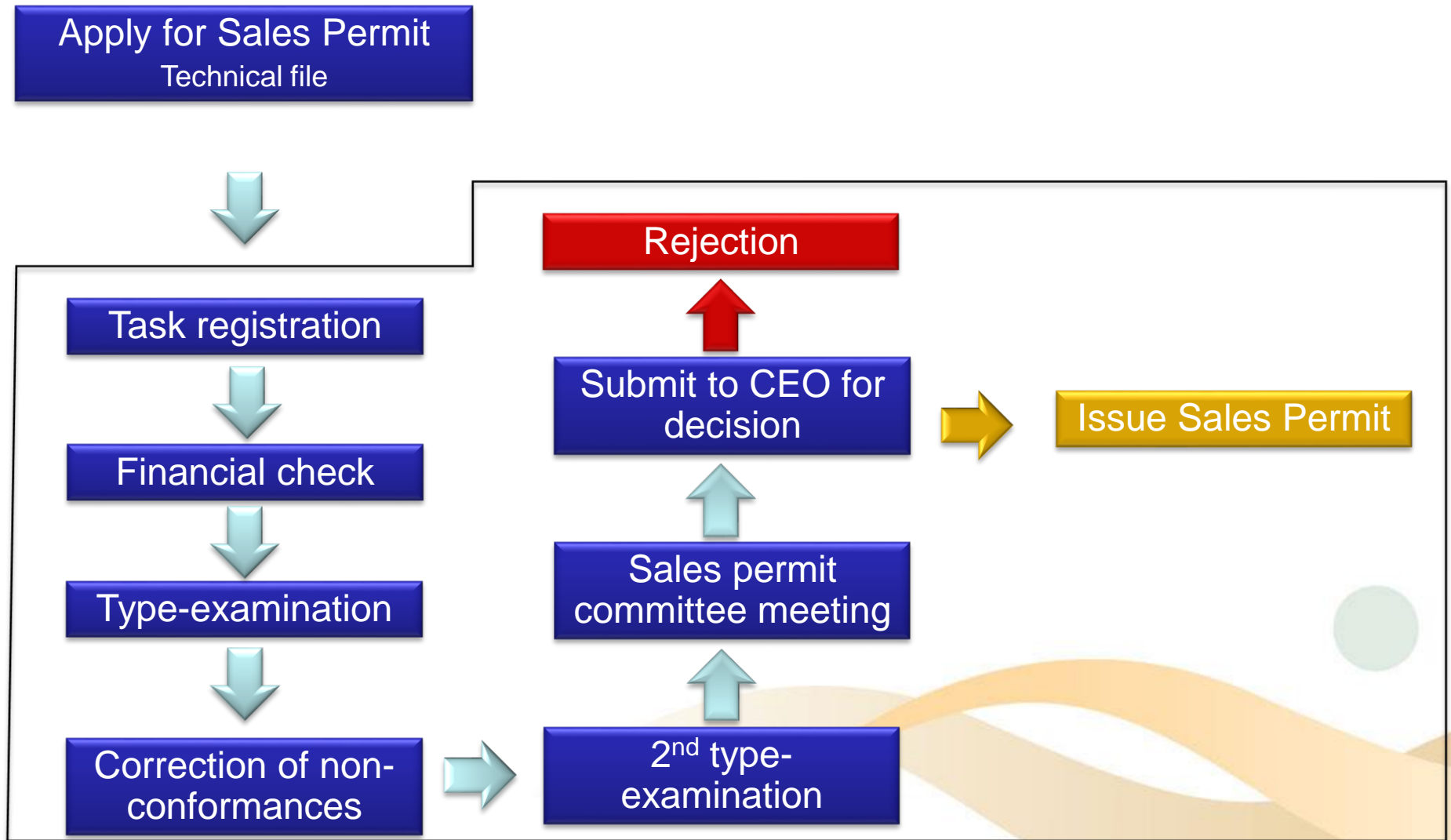
14. (2) No person may import, sell or supply a commodity, product or service to which a compulsory specification applies, unless—

(a) the commodity, product or service complies with, or has been manufactured in accordance with, the compulsory specification, or both

(4) The National Regulator may issue a sales permit exempting the person to whom it has been issued from complying with subsection (2)(a).

- *During the Covid-19 pandemic, The NRCS is utilizing this clause to process and fast track approval of masks and Chemical Disinfectants which don't fully comply with the requirements of the Compulsory Specifications VC8054:2017 and VC8072:2011*

SALES PERMIT PROCESS



Thank you