

Minimum safety regulations for microbiological safety cabinets in South Africa

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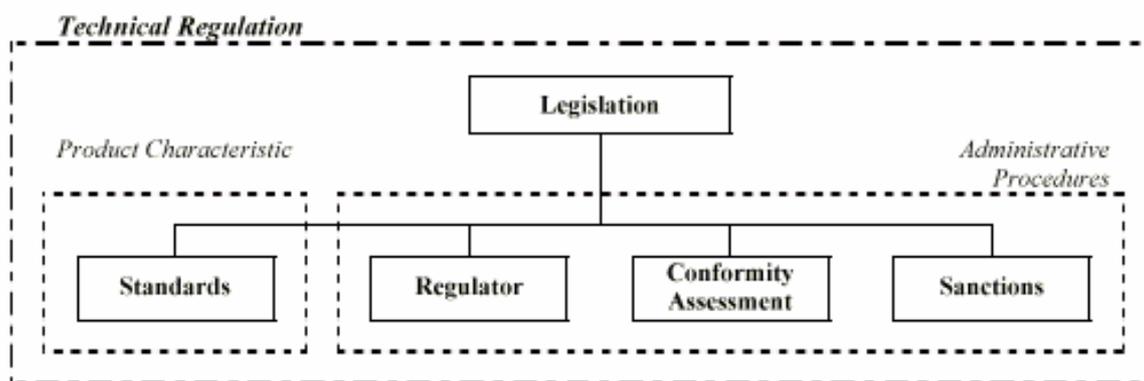
1. Introduction

These minimum safety regulations apply to all types of microbiological safety cabinets as covered by the scope of the Compulsory Specification for biological safety cabinets (Classes I, II and III) (herein referred to as VC8041:2001) as published by Government Notice No. R. 93 (Government Gazette No. 22014) of 2 February 2001.

A type of microbiological safety cabinet (MSC) can be defined as a category of cabinet that does not differ in such essential respects as:

- the trade name or mark, or;
- the design, materials, dimensions, manufacturing processes, operating method or methods of assembly.

The importation, sale and supply of MSCs are regulated in the Republic of South Africa by means of the Technical Regulation Best Practice Model.



The Technical Regulation Best Practice Model was developed to comply with World Trade Organization/Technical Barriers to Trade (WTO/TBT) requirements; i.e. to protect the consumer through technical regulations without creating a technical barrier to trade.

2. Technical regulations

A technical regulation in terms of Act No. 5 of 2008 is a South African National Standard or a provision of a South African National Standard that has been declared compulsory by means of a notice in the Government Gazette in terms of section 13 of Act No. 5 of 2008 by the Minister of Trade & Industry. Such a technical regulation is defined as a compulsory specification in terms of section 1 of Act No. 5 of 2008.

In accordance with the definitions in section 1 and the requirements of section 14 of Act No. 5 of 2008, no person may import, display, offer, advertise or export for or in pursuance of a sale, have in possession for the purpose of sale, trade, manufacture or export, or supply a commodity, product or service to which a compulsory specification applies, unless such a commodity, product or service complies with the compulsory specification concerned. All MSCs that are sold, manufactured and supplied in, imported into and exported from the Republic of South Africa shall comply with VC8041:2001.

In accordance with regulation 2.1 as published by Government Notice No. R. 999 (Government Gazette No. 9728) of 3 May 1985, the manufacturer or importer shall keep accurate records in respect of the number of MSC units manufactured or imported.

In accordance with the regulations relating to the payment of levy and the issue of sales permits in regard to compulsory specifications as published by Government Notice No. R. 999 (Government Gazette No. 9728) of 3 May 1985, and amended by Government Notice No. 2242 (Government Gazette No. 14190) of 7 August 1992 and Government Notice No. R. 451 (Government Gazette No. 24623) of 4 April 2003, the manufacturer or importer shall pay the prescribed levies as published from time to time in the Government Gazette to the NRCS on the first day of the month following the expiry of each levy period on the number of MSC units manufactured or imported. The levy periods are 01 April – 31 June, 01 July – 30 September, 01 October – 31 December and 01 January – 31 March of each South African Government financial year.

Manufacturers and importers of MSCs are advised to inform their suppliers, distributors and retailers of the abovementioned requirements.

3. Legislation

Legislation is the mechanism through which Government may implement its policy with regard to safety, health, environmental control and consumer protection as it relates to the supply of commodities in the market place.

The National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) came into effect on 1 September 2008. The purpose of Act No. 5 of 2008 is to provide a legal framework for the administration and maintenance of compulsory specifications in the interest of public safety and health and for environmental protection in the Republic of South Africa, and to establish the National Regulator (NRCS) to administer such compulsory specifications. Therefore, the Division administers VC8041:2001 in terms of the provisions and requirements of Act No. 5 of 2008.

NRCS Chemicals, Mechanical & Materials Division

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"Protecting health, Safety, the Environment and ensuring Fair Trade"

4. Product characteristics

4.1 Standards

South Africa has harmonised its National Standard for MSCs, SANS 12469:2002, with European Standard EN 12469:2000: "Biotechnology — Performance criteria for microbiological safety cabinets". However, compliance with the requirements of SANS 12469:2002 is voluntary.

Compliance with the requirements of VC8041:2001 is mandatory.

5. Administrative procedures

5.1 Regulator

The NRCS was established in terms of Act No. 5 of 2008 for the administration and maintenance of compulsory specifications and the implementation of a regulatory and compliance system for compulsory specifications.

The Chemicals, Mechanical & Materials Division (CMM) of the NRCS is responsible for the administration of VC8041:2001.

5.2 Conformity assessments

The conformity assessment process provides evidence to the Regulator of the extent to which a commodity, product or service complies with a technical regulation.

The conformity assessment processes for MSCs consist of a homologation process and surveillance inspections.

5.2.1 Homologation of MSCs

In order to be in compliance with section 14 of Act No. 5 of 2008, a supplier (importer or manufacturer) must obtain the necessary proof of compliance for a MSC type with the requirements of VC8041:2001 before he may supply such a MSC type in South Africa. Such proof of compliance is a NRCS HOMOLOGATION GRANTED certificate that was issued by the NRCS. Homologation is a confirmation by the NRCS that a MSC type has satisfied all the relevant requirements of VC8041:2001.

Manufacturers and importers who are established within the Republic of South Africa may apply to CMM for the homologation of MSCs. An application for homologation shall consist of the items as set out in NRCS form No. VC8041-E.

A set of application forms consists of the following:

- NRCS form No. VC8041-C;
- NRCS form No. VC8041-E;
- NRCS form No. VC8041-F.

The Manager: Approvals of the NRCS CMM Division can be contacted for further details regarding the homologation process and for the submission of applications for the homologation of MSCs.

A list of homologated MSCs is available at the following internet address: [Homologation Database – MSCs](#).

5.2.2 Surveillance inspections

Surveillance inspections is a function performed by the NRCS whereby its inspectors go out into the market and inspect MSCs at the point of import, sale, supply and use in order to ensure that nobody is importing, selling or supplying MSCs that do not comply with VC8041:2001. The NRCS inspectors conduct surveillance inspections at manufacturers, importers, distributors (e.g. wholesalers), retailers, suppliers and users of MSCs in accordance with sections 17, 18 and 19 of Act No. 5 of 2008.

5.3 Sanctions

The sanctions process is the mechanism used by the Regulator to prevent the availability to the consumer of commodities that do not meet the requirements of the technical regulations.

The following recourses are available to the NRCS to prevent the availability to the public of MSCs that do not meet the requirements of VC8041:2001:

- The CEO of the NRCS may issue a directive in accordance with section 15(1) of Act No. 5 of 2008 to ensure that any person (who may be the manufacturer, importer, distributor, retailer or supplier) who is in possession or control of the non-compliant MSCs, keeps it in his or her possession or under his or her control at or on any premises specified in the directive, and does not tamper with or dispose of it, until the directive is withdrawn by the CEO in writing.
- The Board of the NRCS may take action to ensure the recall of the non-compliant MSCs, direct in writing that the importer of the non-compliant MSCs returns it to its country of origin, or direct in writing that the non-compliant MSCs be confiscated, destroyed or dealt with in such other manner as the Board may consider fit in terms of section 15(3) of Act No. 5 of 2008.
- The NRCS may take legal action against the manufacturer, importer, distributor, retailer, or supplier of non-compliant MSCs in accordance with section 34 of Act No. 5 of 2008.
- Press releases to warn the public of non-compliant MSCs in accordance with section 29 of Act No. 5 of 2008.

6. Consumer recourse

Any individual or organization may contact the NRCS CMM Division concerning suspected non-complying MSCs that may be available in the market. When reporting such concerns of suspected non-complying MSCs, the following information will be required by the NRCS:

- Full description of the suspected non-complying MSC type.
- Name of the importer, seller or supplier who has supplied the MSC type.
- Physical address and contact details of the importer, seller or supplier.

Reporters are advised to keep the following evidence:

- Proof of purchase or other delivery documents.
- The product itself.
- All accompanying documentation and packaging.

On receipt of such reports the NRCS will conduct an investigation into the suspected non-complying MSCs in terms of the powers vested in accordance with Act No. 5 of 2008. The NRCS will take any actions needed that may be necessary in terms of vested powers in accordance with Act No. 5 of 2008 to prevent the availability of non-complying MSCs to the consumer.

The reporter will be notified of the outcome of the investigation verbally (if the concern was received verbally) or in writing (if the concern was received in writing) within the limits of Section 32 of Act No. 5 of 2008.

Please note that the name of the person or organisation reporting a concern to the NRCS will not be divulged to the alleged contravener, unless specifically authorised by the reporter.

7. Sales Permits

In accordance with sections 14(4) and (5) of Act No. 5 of 2008, the NRCS may issue a sales permit exempting the person to whom it has been issued from complying with section 14(2)(a) of Act No. 5 of 2008 for a commodity, product or service that does not comply with, or has not been manufactured in accordance with, an applicable compulsory specification, or for an experimental type approval commodity or product to which a compulsory specification applies.

In accordance with regulation 4.2 as published by Government Notice No. R. 999 (Government Gazette No. 9728) of 3 May 1985, except where resale is specifically prohibited in the conditions subject to which a sales permit has been issued, a sales permit shall also cover the resale of the commodity by a person other than the sales permit holder.

During a meeting that was held with manufacturers and importers of MSCs on 13/08/2007, the Regulatory Executive (now the CEO of the NRCS) of the SABS Regulatory Division (now the NRCS) has indicated that a Sales Permit will be granted for a MSC type provided that the applicant can prove compliance with the appropriate South African National Standard, which is the latest edition of SANS 12469: 'Biotechnology — Performance criteria for microbiological safety cabinets'.

Manufacturers and importers who are established within the Republic of South Africa may apply to CMM for a Sales Permit for a type of MSC that does not meet the requirements of VC8041:2001, but that does comply with the latest edition of SANS 12469. An application for a Sales Permit shall consist of the items as set out in NRCS form No. VC8041-A.

A set of application forms consists of the following:

- Application form for a Sales Permit;
- NRCS form No. VC8041-A;
- NRCS form No. VC8041-B.

The Manager: Approvals of the NRCS CMM Division can be contacted for further details regarding the Sales Permit application process and for the submission of applications.

8. Contacts

8.1 Applications for homologation and Sales Permits

Mrs. Tando Magolego
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NRCS CMM DIVISION
Tel No.: +27 12 428-6375
Fax No.: +27 12 428 6513
E-mail: MAGOLET@nrcs.org.za

8.2 Consumer recourse

Mr. Hendrik F. de Kock
MANAGER: CMM REGIONS
NRCS CMM DIVISION
Tel No.: +27 (012) 428-6585
Fax No.: +27 12 428-6513
E-mail: DEKOCKHF@nrcs.org.za

8.3 Information and purchasing of South African National Standards

SABS Standards Information Centre

Telephone Number:
National: (012) 428-6666
International: +27 12 428-6666

Fax Number:
National: (012) 428-6928
International: +27 12 428-6928

Email: info@sabs.co.za

Centre hours: 07:30 – 17:00