

5337 E004

NRCS CMM Div. – Homologation of respiratory protective devices

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Date of approval:	09/03/2011		
Date of implementation:	15/03/2011		

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1 Purpose

In accordance with the General Safety Regulations under the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), and the Regulations under the Mine Health and Safety Act, 1996 (Act No. 29 of 1996) all respiratory protective devices must be submitted to the NRCS for homologation in accordance with SANS 10338.

This document describes the procedure that is used by CMM for the administration of SANS 10338.

2 Scope

This document applies to the following:

- a) All staff members of CMM involved in the homologation of RPDs.
- b) All respiratory equipment as covered by the scope of SANS 10338.

This document covers the following:

- a) General requirements for the homologation of RPDs.
- b) Application for the homologation of RPDs.
- c) Type-examination of RPDs.
- d) Refusal of homologation for RPDs.
- e) Homologation granted for RPDs.
- f) Extension of homologation for RPDs.
- g) Withdrawal of homologation for RPDs.

This document should be read in conjunction with SANS 10338.

3 References

This document incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text. For dated references, subsequent amendments to or revisions of any of these publications apply to this document only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

3.1 Manuals

Divisional Manual No. CMM M003: *'Quality Management System'*

3.2 Standards

SANS 10338: *'Homologation of respiratory equipment'*

SANS 9001: *'Quality management systems - Requirements'*.

SANS 17021: *'Conformity assessment – Requirements for bodies providing audit and certification of management systems'*

SANS 17025: *'General requirements for the competence of testing and calibration laboratories'*

3.3 Legislation

Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) and General Safety Regulations

Government Notice No. R. 736 as published in Government Gazette No. 22565 of 1 September 2001.

Mine Health and Safety Act, 1996 (Act No. 29 of 1996) and Regulations

Government Notice No. R. 904 as published in Government Gazette No. 23583 of 2 July 2002.

National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008)

Regulation 2 relating to the payment of fees in the form of levies as published by Government Notice No. R. 924 (Government Gazette No. 33615) of 15 October 2010.

4 Definitions & abbreviations

4.1 Definitions

Applicant: The manufacturer or importer of a RPD type. The manufacturer or importer shall be established within the Republic of South Africa.

Breathing apparatus: As defined in SANS 10338.

Homologation: As defined in SANS 10338.

IAF accredited certification authority: A body that has been accredited in accordance with SANS 17021 by an organization that is part of the IAF Mutual Recognition Agreement.

ILAC-accredited testing authority: A laboratory that has been accredited in accordance with SANS 17025 or equivalent standard, by an organization that is part of the ILAC Mutual Recognition Arrangement.

Inspector: A staff member of CMM responsible for the homologation of *respiratory protective equipment* and *breathing apparatus*.

Respiratory protective device: BA or RPE as defined in SANS 10338.

Respiratory protective equipment: As defined in SANS 10338.

RPD type: A category of RPD that does not differ in such essential respects as:

- a) the trade name or mark, or
- b) the shape, materials, dimensions, manufacturing processes or methods of assembly. However, a RPD type may include a range of facepiece sizes, provided that the dimensions of each size in the range is at least equal to that in the facepiece sample which when subjected to the homologation tests satisfied the requirements of the applicable product specification standard.

Technical file: A collection of documents as indicated in Appendix A.4 or a collection of parts thereof.

Type-examination: is the procedure whereby CMM establishes that sufficient data was submitted for the identification of a type of RPD and its components, that the type of RPD satisfied the requirements of the appropriate South African National Standard, and that the type of RPD is imported or manufactured under a quality management system applied by the manufacturer or importer that satisfies the requirements of SANS 9001.

4.2 Abbreviations

BA: Breathing Apparatus

CMM: NRCS Chemicals, Mechanical & Materials Division

IAF: International Accreditation Forum

ILAC: International Laboratory Accreditation Co-operation

RPD: *respiratory protective device*

RPE: *respiratory protective equipment*

5 General requirements

5.1 Proof of compliance

5.1.1 Criteria

5.1.1.1 A RPD product shall be examined for compliance with an appropriate South African National Standard for RPDs.

5.1.2 Evidence

5.1.2.1 Only test reports from an ILAC accredited testing authority shall be accepted as proof of compliance with the constructional and performance requirements of an appropriate South African National Standard for RPDs. Test reports shall meet the requirements of SANS 17025. No approval certificates shall be accepted.

5.2 Proof of production conformance

5.2.1 Only certification certificates from a certification authority that has been accredited in accordance with SANS 17021 by an organization that is part of the IAF Mutual Recognition Agreement shall be acceptable. The certification certificates shall still be valid on the date of receipt and shall indicate that the quality management system introduced by the manufacturer or importer satisfies the requirements of SANS 9001 or equivalent standard.

5.2.2 Certification certificates shall satisfy the requirements of SANS 17021.

5.3 Samples

5.3.1 Reference samples for homologation purposes shall be stored in room C225.

5.3.2 Reference samples in accordance with subsection 4.5 of SANS 10338 shall be kept in room C225 until collected by the applicant.

5.3.3 An AA33 form shall be completed and issued to the applicant:

- a) On receipt of application documents and reference samples from the applicant.
- b) When the applicant or his agent collects application documents and reference samples from CMM.

A copy of the AA33 form shall be kept in the relevant client file or product file.

5.4 Data

5.4.1 *Homologation Database PPE* is stored on the NRCS computer network and shall be maintained by the Manager: Approvals.

5.4.2 *Technical File Database* is stored on the NRCS computer network and shall be maintained by the Manager: Approvals.

5.5 Records

5.5.1 Product files shall be kept in room C225 until withdrawal of homologation (see paragraph 11). The Manager: Approvals shall be responsible for the maintenance of such product files.

5.5.2 All records pertaining to the homologation of a type of RPD shall be kept in the applicable homologation file. Records shall be kept for all documentation generated and received during the execution of this procedure. The records to be kept are identified in this procedure.

5.5.3 The client files are kept in room C314A and are indexed according to "Respiratory protective devices: Levy Payers" (manufacturers and importers of RPD) and "Respiratory protective devices: Distributors"

(distributors and retailers of RPD). The contents of the client files shall be kept for a period of at least three (3) years after which it may be disposed of by means of waste disposal on instruction from the Manager: CMM Regions (see paragraph 12.3.2 of Divisional Manual No. CMM M003).

5.6 Communications

All communications may be verbally, telephonically, electronically or in writing, except where otherwise stated in this document.

5.7 Inspection safety

Care shall be taken when handling RPD samples for examination purposes, as a risk of personal injury may exist as a result of possible sharp edges, parts under pressure and chemical reactions.

6 Application for homologation

SANS 10338, subsection 3.1

- 6.1 The applicant may request for the homologation of a type of RPD as per subsection 3.1 of SANS 10338.

SANS 10338, subsection 3.2

- 6.2 On receipt of an application in accordance with subsection 3.1 of SANS 10338, or on request, the inspector shall determine if the product is covered by the scope of an appropriate South African National Standard for RPDs.

6.3 Product not covered by South African National Standard

- 6.3.1 Should it be found that the product is not covered by the scope of an appropriate South African National Standard, the inspector shall inform the applicant accordingly (electronically or in writing). The inspector shall file the following in the relevant client file (see paragraph 5.5.3):

- a) A copy of the abovementioned communication to the applicant.
- b) Documented evidence (e.g. technical specifications, instructions for use manuals, marketing material, etc.) that indicates that the product is not covered by the scope of an appropriate South African National Standard for RPDs.

6.4 Product covered by South African National Standard

When it is found that the product is covered by the scope of an appropriate South African National Standard, the inspector or Administration Officer: Approvals shall issue a set of homologation documents as set out in Annexure A to the applicant.

SANS 10338, subsection 3.3

- 6.5 The applicant will submit the items as communicated to him by means of NRCS form No. VC8072-A.1 to CMM.

6.6 Registration of application

On receipt of the application, the Administration Officer: Approvals shall take the following actions:

- 6.6.1 The application shall be registered in the *Technical File Database - PPE*.
- 6.6.2 A homologation file shall be opened. The homologation file and all relevant documentation in the technical file shall be marked with the technical file number.
- 6.6.3 The sample (when available) shall be marked with the technical file number.

6.7 Financial check

- 6.7.1 The Administration Officer: Approvals shall ensure with the Finance Division of the NRCS that the applicant has been registered as a levy payer in terms of regulation 2 relating to the payment of fees in the form of levies as published by Government Notice No. R. 924 (Government Gazette No. 33615) of 15 October 2010.

- 6.7.2 The Administration Officer: Approvals shall check for the following:

- a) If the applicant has included proof of payment of the non-refundable application fee for the homologation of the type of RPD.
- b) If the applicant's levy return forms and payments are up to date (check with the Finance Division of the NRCS).
- c) If the applicant owes any other outstanding fees to the NRCS (check with the Finance Division of the NRCS).

- 6.8** When it is found that the applicant has not met his financial obligations towards the NRCS as set out in paragraph 6.7.2, the Administration Officer: Approvals shall take the following actions:
- 6.8.1** *Application without proof of payment*
- The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the due application fee for homologation. A copy of the invoice shall be filed in the homologation file.
- 6.8.2** The applicant shall be informed electronically or in writing of the following:
- a) The application for the homologation of the type of RPD will not be considered, because of the outstanding proof of payment of the non-refundable application fee or other outstanding fees.
 - b) The application will be rejected if no proof of payment of the outstanding fee/s has been received within three (3) weeks from the date of notification.
- 6.8.2.1** The Administration Officer: Approvals shall file a copy of the notification in the relevant homologation file.
- 6.8.3** The actions as set out in paragraph 8 may be taken when no proof of payment of the outstanding fee/s has been received within the three (3) week notification period.
- 6.9** When it is found that the applicant has met his financial obligations towards the NRCS, the Administration Officer: Approvals shall take the following actions:
- 6.9.1** The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the received proof of payment of the non-refundable application fee. The Administration Officer: Approvals shall file a copy of the invoice indicating full payment of the application fee in the relevant homologation file.
- 6.9.2** The Administration Officer: Approvals shall forward the homologation file to the inspector who has been nominated by the Manager: Approvals to examine the application.

7 Type-examination of RPDs

SANS 10338, subsections 3.4

7.1 The technical file and its contents shall be examined for completeness and correctness.

The technical file and its contents shall be examined to establish its suitability with respect to demonstrating compliance with the appropriate South African National Standard and SANS 9001.

The results of the examination shall be recorded in a *NRCS Inspection Report* for RPDs as attached to this document.

7.2 Unacceptable technical file

The inspector shall take the following actions should the technical file and its contents not meet the criteria as set out in paragraph 7.1:

7.2.1 The inspector shall notify the applicant electronically or in writing of the following:

- a) The applicant shall be notified of the problems with the technical file and requested to resubmit a corrected file within four (4) months from the date of notification.
- b) The technical file and reference sample (when available) must be collected at the NRCS premises for correction purposes.

7.2.2 The inspector shall file copies of the notification and technical file in the homologation file.

7.3 The actions as set out in paragraph 8 shall be taken should the applicant fail to resubmit the corrected technical file within the four (4) month period.

7.4 The following actions shall be taken when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 7.1:

7.4.1 One copy of the technical file shall be made and kept in the homologation file.

7.4.2 The inspector shall invite the applicant to a meeting at the NRCS premises. The purpose of the meeting will be the following:

- a) Explanation of the findings on the technical file.
- b) The applicant shall be supplied with a copy of the findings.
- c) The inspector shall return the technical file and reference sample (when available) to the applicant during the meeting for correction purposes.
- d) The applicant shall be requested to resubmit a corrected technical file within three (3) weeks from the date of the meeting.

7.4.3 The actions as set out in paragraph 8 shall be taken should:

- a) the applicant fail to resubmit the corrected technical file within the three (3) week period after the meeting or;
- b) when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 7.1.

SANS 10338, subsections 3.5

7.5 Acceptable technical file

The following actions shall be taken when the technical file meets the criteria as set out in paragraph 7.1:

7.5.1 Should a sample of the respiratory protective equipment or breathing apparatus product not be received, the applicant shall be notified of the examination date of the reference sample. The applicant shall also be requested to deliver the sample before the examination date.

7.5.2 The actions as set out in paragraph 8 shall be taken should the applicant fail to submit the correct sample of the respiratory protective equipment or breathing apparatus product before the examination date.

SANS 10338, subsections 3.6

7.5.3 The inspector shall examine the sample of the type of RPD in order to verify that it has been produced in accordance with the technical file. The results of the examination shall be recorded in the *NRCS Inspection Report* for RPDs.

7.6 Unacceptable reference sample

7.4.1 The actions as set out in paragraph 8 shall be taken should the reference sample not meet the criteria as set out in paragraph 7.5.3.

7.7 Acceptable reference sample

7.7.1 The actions as set out in paragraph 9 shall be taken when the sample meets the criteria as set out in paragraph 7.5.3.

8 HOMOLOGATION REJECTED

- 8.1** The inspector shall complete and sign the inspection report and include it in the homologation file.
- 8.2** The inspector shall prepare a letter as set out in Annexure B and include it in the homologation file.
- 8.3** The inspector shall forward the homologation file to the Manager: Approvals for review.
- 8.4** Once satisfied with the contents of the inspection report and letter, the Manager: Approvals shall sign the aforementioned documents.
- 8.5** The inspector shall file copies of the following documents in the homologation file:
- a) The signed letter in paragraph 8.4;
 - b) *NRCS Inspection Report*;
 - c) Technical file (when available).
- 8.6** The inspector shall ensure that the signed letter in paragraph 8.4 is forwarded to the applicant electronically or by mail.
- 8.7 Close-out of homologation task**
- 8.7.1** The inspector shall file the homologation file in the relevant client file.

9 HOMOLOGATION GRANTED

- 9.1** The inspector shall complete and sign the inspection report. The inspection report shall be filed in the homologation file.
- 9.2** The inspector shall register the type of RPD in the *Homologation Database PPE* and shall allocate a type approval number.

9.3 Homologation certificate

- 9.3.1** The inspector shall compile a *NRCS HOMOLOGATION GRANTED certificate* as attached to this document.
- 9.3.2** The inspector shall mark the following documents with the allocated type approval number and initial it:
- Technical description supported by technical drawings of the type of respiratory protective device. This may include photographic evidence and diagrams when available; **Note: Where possible, the inspector shall include a sectional piece of the filter media used in the filter of the RPD for homologation.**
 - Details of the marking of the type of respiratory protective device;
 - Details of the marking of the packaging for the type of respiratory protective device;
 - Information for users for the type of respiratory protective device.

The documents shall be described in the *NRCS HOMOLOGATION GRANTED certificate*.

- 9.3.3** The inspector shall emboss the golden star on the certificate with the NRCS emblem embossment machine.
- 9.3.4** The inspector shall sign the prepared *NRCS HOMOLOGATION GRANTED certificate* and include it in the homologation file.
- 9.4** The inspector shall forward the homologation file to the Manager: Approvals for review.
- 9.5** Once satisfied with the contents of the inspection report and *NRCS HOMOLOGATION GRANTED certificate*, the Manager: Approvals shall sign the aforementioned documents.
- 9.6** The inspector shall compile the following:

<p>ORIGINAL <i>NRCS HOMOLOGATION GRANTED certificate</i></p> <p>↓</p> <p>Attach to ORIGINAL certificate: COPIES of marked documents in paragraph 9.3.2.</p> <p>↓</p> <p>Submit to applicant.</p>	<p>COPY of <i>NRCS HOMOLOGATION GRANTED certificate</i></p> <p>↓</p> <p>Attach to COPY of certificate: ORIGINAL marked documents in paragraph 9.3.2.</p> <p>↓</p> <p>File in homologation file.</p>
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- 9.7** The inspector shall attach a label to the reference sample indicating the following information:
- Type approval number that was allocated to the homologated type of RPD;
 - Signature of the inspector.
- 9.8** The inspector shall notify the applicant in writing or by e-mail that the approved *NRCS HOMOLOGATION GRANTED certificate* and reference sample must be collected at the NRCS premises. The inspector shall file a copy of the aforementioned notification in the homologation file.
- 9.9** The inspector shall open a product file for the homologated type of RPD and mark it with the allocated type approval number.

- 9.10** The inspector shall file the homologation file in the product file for the homologated type of RPD.
- 9.11** The inspector shall store the product file in room C225.

10 Extension of homologation

10.1 Notification

10.1.1 In accordance with the terms and conditions of issue of a *NRCS HOMOLOGATION GRANTED certificate* for RPDs the holder of a homologation shall notify the NRCS of any modifications that will be made to a homologated type of respiratory protective device itself, its design and materials, marking, packaging material and information notices that must accompany it when placed on the market as required by the appropriate South African National Standard.

10.1.2 The inspector shall establish the nature of the changes made to the homologated type of RPD, and request in writing or electronically the following from the applicant:

- a) A letter from the applicant indicating the modifications that will be made to the homologated type of respiratory protective device.
- b) Proof of payment of the current non-refundable application fee for the extension of homologation of a type of RPD as published in the Government Gazette in terms of section 14(3)(b) of Act No. 5 of 2008.
- c) Documented evidence as per NRCS form No. VC8072-A.4 indicating such changes.
- d) A specimen of the type of RPD if modifications were made to the product itself, its design and materials and/or markings.

10.2 Registration of application

10.2.1 On receipt of the items as per paragraph 10.1.2, the Administration Officer: Approvals shall take the following actions:

10.2.1.1 The application shall be registered in the *Technical File Database - PPE*.

10.2.1.2 A homologation file shall be opened. The homologation file and all relevant documentation in the technical file shall be marked with the technical file number.

10.2.1.3 The sample (when available) shall be marked with the technical file number.

10.3 Financial check

10.3.1 The Administration Officer: Approvals shall check for the following:

- a) If the applicant has included proof of payment of the non-refundable application fee for the extension of homologation of the type of RPD.
- b) If the applicant's levy return forms and payments are up to date (check with the Finance Division of the NRCS).
- c) If the applicant owes any other outstanding fees to the NRCS (check with the Finance Division of the NRCS).

10.4 When it is found that the applicant has not met his financial obligations towards the NRCS as set out in paragraph 10.3.1, the Administration Officer: Approvals shall inform the applicant electronically or in writing of the following:

- a) The application for the extension of homologation of the type of RPD will not be considered, because of the outstanding proof of payment of the non-refundable application fee or other outstanding fees.
- b) The application will be rejected if no proof of payment of the outstanding fee/s has been received within three (3) weeks from the date of notification.

10.4.1 The Administration Officer: Approvals shall file a copy of the notification in the relevant homologation file.

10.4.2 The actions as set out in paragraph 8 may be taken when no proof of payment of the outstanding fee/s has been received within the three (3) week notification period.

- 10.5** When it is found that the applicant has met his financial obligations towards the NRCS, the Administration Officer: Approvals shall take the following actions:
- 10.5.1 The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the received proof of payment of the application fee. The Administration Officer: Approvals shall file a copy of the invoice indicating full payment of the application fee in the relevant homologation file.
- 10.5.2 The Administration Officer: Approvals shall forward the homologation file to the inspector who has been nominated by the Manager: Approvals to examine the application.

10.6 Type-examination

- 10.6.1 The technical file and its contents shall be examined to establish its suitability with respect to demonstrating the following:
- a) Modifications made to the type of RPD itself, its design and materials, markings, packaging material and information for users that shall accompany it when placed on the market as required by the appropriate South African National Standard.
 - b) Compliance with the appropriate South African National Standard as a result of the modifications made.

The results of the examination shall be recorded in a *NRCS Inspection Report* for RPDs.

10.7 Unacceptable technical file

The inspector shall take the following actions should the technical file and its contents not meet the criteria as set out in paragraph 10.6.1:

- 10.7.1 The inspector shall notify the applicant electronically or in writing of the following:
- c) The applicant shall be notified of the problems with the technical file and requested to resubmit a corrected file within four (4) months from the date of notification.
 - d) The technical file and reference sample (when available) must be collected at the NRCS premises for correction purposes.
- 10.7.2 The inspector shall file copies of the notification and technical file in the homologation file.
- 10.7.3 The actions as set out in paragraph 8 shall be taken should the applicant fail to resubmit the corrected technical file within the four (4) month period.
- 10.7.4 The following actions shall be taken when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 10.6.1:
- 10.7.4.1 One copy of the technical file shall be made and kept in the homologation file.
- 10.7.4.2 The inspector shall invite the applicant to a meeting at the NRCS premises. The purpose of the meeting will be the following:
- a) Explanation of the identified non-conformances on the technical file.
 - b) The applicant shall be supplied with a copy of the identified non-conformances.
 - c) The inspector shall return the technical file and reference sample (when available) to the applicant during the meeting for correction purposes.
 - d) The applicant shall be requested to resubmit a corrected technical file within three (3) weeks from the date of the meeting.
- 10.7.4.3 The actions as set out in paragraph 8 shall be taken should:
- a) the applicant fail to resubmit the corrected technical file within the three (3) week period after the meeting or;

- b) when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 10.6.1.

10.8 Acceptable technical file

The following actions shall be taken when the technical file meets the criteria as set out in paragraph 10.6.1:

- 10.8.1 When modifications were made to the type of RPD itself, its design and materials and/or markings, the inspector shall examine a reference sample of the type of RPD in order to verify that it has been produced in accordance with the modifications demonstrated in the technical file. The results of the examination shall be recorded in the *NRCS Inspection Report* for RPDs.

10.9 Unacceptable reference sample

- 9.9.1 The actions as set out in paragraph 8 shall be taken should the reference sample not meet the criteria as set out in paragraph 10.8.1.

10.10 Acceptable reference sample

- 10.10.1 The actions as set out in paragraph 10.11 shall be taken when the sample meets the criteria as set out in paragraph 10.8.1.

10.11 HOMOLOGATION EXTENDED

- 10.11.1 The inspector shall complete and sign the inspection report. The inspection report shall be filed in the homologation file.
- 10.11.2 The inspector shall register the extension of homologation of the type of RPD in the *Homologation Database PPE* and shall assign a sequential "Extension No.". The Extension Number shall be in Roman numerals, e.g. I, II, III, etc.

10.12 Extension of homologation certificate

- 10.12.1 The inspector shall compile a *NRCS HOMOLOGATION EXTENDED certificate* for RPDs as attached to this document.
- 10.12.2 The inspector shall mark the following documents with the appropriate type approval number and initial it:
- a) When relevant, technical descriptions supported by technical drawings demonstrating the modifications made to the type of respiratory protective device itself and its design and materials. This may include photographic evidence and diagrams when available; **Note: Where possible, the inspector shall include a sectional piece of the filter media used in the filter of the RPD.**
 - b) When relevant, details of the modifications made to the marking of the type of respiratory protective device;
 - c) When relevant, details of the modifications made to the marking of the packaging for the type of respiratory protective device;
 - d) When relevant, details of the modifications made to the information for users for the type of respiratory protective device.

The relevant documents and alterations shall be described in the *NRCS HOMOLOGATION EXTENDED certificate*.

- 10.12.3 The inspector shall emboss the golden star on the *NRCS HOMOLOGATION EXTENDED certificate* with the NRCS emblem embossment machine.
- 10.12.4 The inspector shall sign the prepared *NRCS HOMOLOGATION EXTENDED certificate* and include it in the homologation file.

- 10.13** The inspector shall forward the homologation file to the Manager: Approvals for review.
- 10.14** Once satisfied with the contents of the inspection report and *NRCS HOMOLOGATION EXTENDED certificate*, the Manager: Approvals shall sign the aforementioned documents.
- 10.15** The inspector shall compile the following:

<p>ORIGINAL <i>NRCS HOMOLOGATION EXTENDED certificate</i></p> <p style="text-align: center;">↓</p> <p>Attach to ORIGINAL certificate: COPIES of marked documents in paragraph 10.12.2.</p> <p style="text-align: center;">↓</p> <p>Submit to applicant.</p>	<p>COPY of <i>NRCS HOMOLOGATION EXTENDED certificate</i></p> <p style="text-align: center;">↓</p> <p>Attach to COPY of certificate: ORIGINAL marked documents in paragraph 10.12.2.</p> <p style="text-align: center;">↓</p> <p>File in homologation file.</p>
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- 10.16** The inspector shall notify the holder of the homologation in writing or by e-mail that the approved *NRCS HOMOLOGATION EXTENDED certificate* must be collected at the NRCS premises. The inspector shall file a copy of the aforementioned notification in the homologation file.
- 10.17** The inspector shall file the homologation file in the appropriate product file for the type of RPD.
- 10.18** The inspector shall store the product file in room C225.

11 HOMOLOGATION WITHDRAWN

11.1 Conditions for the withdrawal of homologation

11.1.1 In accordance with paragraph 4.4 of SANS 10338 the NRCS reserves the right to withdraw a type approval number and homologation certificate for a homologated type of RPD.

11.1.2 The Manager: Approvals shall withdraw the type approval number and homologation certificate for a homologated type of RPD under the following conditions:

- a) Request for the withdrawal of homologation for a homologated type of RPD by the CMM surveillance inspection sections by means of the issuing of a Directive in terms of section 15(1) of Act No. 5 of 2008 against the holder of the homologation.

11.2 The Manager: Approvals shall delete the type approval number and related product information from the *Homologation Database PPE*.

11.3 Withdrawal of homologation certificate

11.3.1 The inspector shall compile a *NRCS HOMOLOGATION WITHDRAWN certificate* as attached to this document.

11.3.2 The inspector shall mark the following documents with the appropriate type approval number and initial it:

- a) Documented evidence of the actions of the CMM surveillance inspection sections as referred to in paragraph 11.1.2 of this document.

The documents shall be described in the *NRCS HOMOLOGATION WITHDRAWN certificate*.

11.3.3 The inspector shall emboss the red star on the *NRCS HOMOLOGATION WITHDRAWN certificate* with the NRCS emblem embossment machine.

11.4 The inspector shall sign the prepared *NRCS HOMOLOGATION WITHDRAWN certificate* and forward it to the Manager: Approvals for review.

11.5 Once satisfied with the contents of the *NRCS HOMOLOGATION WITHDRAWN certificate*, the Manager: Approvals shall sign the aforementioned document.

11.6 The inspector shall compile the following:

<p>COPY of <i>NRCS HOMOLOGATION WITHDRAWN certificate</i></p> <p style="text-align: center;"></p> <p>Submit to applicant.</p>	<p>ORIGINAL <i>NRCS HOMOLOGATION WITHDRAWN certificate</i></p> <p style="text-align: center;"></p> <p>Attach to ORIGINAL certificate: ORIGINAL marked documents in paragraph 11.3.2.</p> <p style="text-align: center;"></p> <p>File in homologation file.</p>
--	--

11.7 The inspector shall submit the following to the holder of the homologation:

11.7.1 A COPY of the *NRCS HOMOLOGATION WITHDRAWN certificate*;

11.7.2 An electronic or written notification containing the following information as a minimum:

- a) In terms of the provisions of the Mine Health and Safety Act, 1996 (Act No. 29 of 1996), the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) and the homologation conditions as set out in paragraph 4 of the latest edition of SANS 10338, the homologation and type approval number for the homologated type of RPD has been withdrawn in accordance with paragraph 4.4 of the latest edition of SANS 10338.
- b) The reasons for the withdrawal of homologation.
- c) In accordance with paragraph 4.4 of the latest edition of SANS 10338, the holder of the homologation is instructed to return all NRCS HOMOLOGATION GRANTED/EXTENDED certificates bearing the applicable type approval number to the following address:

NRCS Chemicals, Mechanical & Materials Division
SABS Campus
1 Dr. Lategan Road
Groenkloof
Pretoria

OR

NRCS Chemicals, Mechanical & Materials Division
Private Bag X25
BROOKLYN
0075

- d) It will be an offence in terms of the provisions of the Mine Health and Safety Act, 1996 (Act No. 29 of 1996) and the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) to use the type of respiratory protective device as identified in the notification in the workplace.

Note: The Manager: Approvals may notify the Department of Labour and the Department of Minerals & Energy of the withdrawal of homologation.

11.8 The inspector shall file the following in the appropriate product file:

- a) The approved *NRCS HOMOLOGATION WITHDRAWN certificate* with attachment documents.
- b) A copy of the notification as set out in paragraph 11.7.2.

11.9 The inspector shall file the product file in the appropriate client file.

12 Replacement and withdrawal

Not applicable.

13 Forms

-

14 Annexures, appendices & attachments

14.1 Annexures & appendices

Annexure A: Homologation documents

Appendix A.1: NRCS form No. VC8072-A.1

Appendix A.3: NRCS form No. VC8072-A.3

Appendix A.4: NRCS form No. VC8072-A.4

Appendix A.5: NRCS form No. VC8072-A5

Annexure B: Letter of HOMOLOGATION REJECTED

14.2 Attachments

AA33: Goods dispatch and receipt note

NRCS Inspection Report for respiratory protective devices.

NRCS HOMOLOGATION GRANTED certificate for respiratory protective devices.

NRCS HOMOLOGATION EXTENDED certificate for respiratory protective devices.

NRCS HOMOLOGATION WITHDRAWN certificate for RPDs.

Annexure A

Homologation documents

A set of homologation documents shall consist of the following:

- A.1** NRCS form No. VC8072-A.1
- A.3** NRCS form No. VC8072-A.3
- A.4** NRCS form No. VC8072-A.4
- A.5** NRCS form No. VC8072-A5

Appendix A.1

NRCS form No. VC8072-A.1



Items required for the homologation of respiratory protective devices

The following items are required for the homologation of a respiratory protective device (RPD) type:

NOTE: All applications, including accompanying documentation, shall be in at least one of the official languages of the Republic of South Africa.

A Application fee

Proof of payment of the non-refundable application fee for the homologation of the type of RPD as published in the Government Gazette in terms of section 14(3)(b) of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008). The amount of the non-refundable application fee may be requested from the NRCS CMM Approvals Section:

Mrs. Tando Magolego
 MANAGER: APPROVALS
 Tel No.: +27 12 428-6375
 Fax No.: +27 12 428 6513
 E-mail: MAGOLEGT@nrcs.org.za

B Technical file

A technical file for the type of RPD as set out in NRCS form No. VC8072-A.4.

C Reference sample

At least one specimen of the type of RPD. The specimen shall include all the accessories that are supplied with the type of RPD, within the packaging, as it is placed on the market, whether or not those accessories have actually been fitted to the RPD.

D Other

Note: An application for the homologation of a type of RPD will not be considered when the applicant owes any outstanding fees to the NRCS, or when the applicant has failed to comply with regulation 2 relating to the payment of fees in the form of levies as published by Government Notice No. R. 924 (Government Gazette No. 33815) of 15 October 2010.

NRCS bank account details:

National Regulator for Compulsory Specifications (NRCS)
 ABSA Bank
 Brooklyn Branch Code: 335345
 Bank Account No.: 4072161682

NRCS Chemicals, Mechanical & Materials Division
 SABS Campus 1 Dr. Lategan Road Groenkloof Pretoria • Private Bag X25 BROOKLYN 0075 • Tel. +27 12 428-6377 • Fax: +27 12 428-6513
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Appendix A.3

NRCS form No. VC8072-A.3



VC8072-A.3

Application for the homologation of a respiratory protective device type

In accordance with SANS 10338:2009.

NOTE: This form shall be completed in full for each type of respiratory protective device submitted for homologation.

Part A: Applicant's details		
Applicant's name:		
Applicant's company registration No.:		
Contact person:	Position in company:	
Tel.:	Fax:	E-mail:
Part B: Importer's details		
Importer's name:		
Postal address:		
Physical address:		
Part C: Manufacturer's details		
Manufacturer's name:		
Postal address:		
Physical address:		
Part D: Product information		
Manufacturer's name or trade mark that appears on the product:		
Model designation:		
Product description:		
South African National Standard applicable to product:		
Product classification:		
Product options:		
Part F: Management declaration		
I hereby certify for and on behalf of the applicant that the information contained in this application and accompanying product technical file is complete and correct in all respects, and is representative of the type of respiratory protective device submitted for homologation.		
Signature:	Name:	
Position in company:	Date:	

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Appendix A.4

NRCS form No. VC8072-A.4

Technical file for respiratory protective devices

The technical file for each type of respiratory protective device (RPD) shall consist of the following:

B.1 Application form

NRCS form No. VC8072-A.3 or any other document that satisfies the requirements of the aforementioned document.

Note: The applicant shall be the manufacturer or importer of the type of RPD. The manufacturer or importer shall be established within the Republic of South Africa.

B.2 Technical specifications

A technical description supported by technical drawings of the type of RPD, indicating the following as a minimum:

- a) All component parts.
- b) Description of each component part.
- c) Material(s) used in each component part.
- d) Methods of assembly.
- e) Colour of the type of RPD.
- f) Marking of the type of RPD as required by the relevant South African National Standard.

Note 1: The technical drawings shall be to scale.

Note 2: Photographic evidence may be included with the technical file in order to support the technical specifications.

B.3 Packaging

Details of the marking of the packaging for the type of RPD as required by the relevant South African National Standard.

B.4 Information notice

Instructions for use/information supplied by the manufacturer for the type of RPD as required by the relevant South African National Standard.

B.5 Proof of compliance

Copies of test reports demonstrating compliance with an appropriate South African National Standard for RPDs, ensuring that all component parts and facepiece sizes (when applicable) have been covered.

Note 1: Only test reports from a testing authority that has been accredited in accordance with the latest edition of SANS 17025 by a signatory to the International Laboratory Accreditation Co-Operation's Mutual Recognition Agreement shall be accepted. No approval certificates shall be accepted.

Note 2: Test reports shall satisfy the requirements of the latest edition of SANS 17025. See NRCS form No. VC8072-A.5 for guidance.

B.6 Quality assurance

Copy of a certificate from a certification authority certifying that the quality management system applied by the manufacturer or importer satisfies the requirements of the latest edition of SANS 9001.

Note 1: Only certification certificates from a certification authority that has been accredited in accordance with the latest edition of SANS 17021 by an organization that is part of the International Accreditation Forum Mutual Recognition Agreement shall be acceptable.

Note 2: Certification certificates shall satisfy the requirements of the latest edition of SANS 17021 and shall still be valid on the date of receipt.

B.7 Other

Any other materials that the applicant may wish to include in the technical file in order to support the application for homologation, e.g. marketing material, photographs and health and safety declarations.

Appendix A.5

NRCS form No. VC8072-A5



Test Reports

Homologation of respiratory protective devices in accordance with SANS 10338:2009.

Test reports for the purpose of homologation of a respiratory protective device type in accordance with SANS 10338:2009 shall contain the following information as a minimum requirement. These requirements are based on the latest edition of SANS 17025 and must be consulted for further guidance.

A	Title: "TEST REPORT".	<input type="checkbox"/>
B	Name and address of laboratory.	<input type="checkbox"/>
C	Test report number.	<input type="checkbox"/>
D	Number of pages contained in the test report.	<input type="checkbox"/>
E	Each page shall be marked with: <ul style="list-style-type: none"> • Test report number • Page number 	<input type="checkbox"/>
F	Name and address of the client.	<input type="checkbox"/>
G	Test and compliance Standard.	<input type="checkbox"/>
H	Product identification.	<input type="checkbox"/>
I	Test dates.	<input type="checkbox"/>
J	Test results against each relevant requirement of the Standard.	<input type="checkbox"/>
K	Statement of compliance/non-compliance.	<input type="checkbox"/>
L	Authorization signatures of laboratory.	<input type="checkbox"/>
M	A statement to the effect that the results relate only to the items tested.	<input type="checkbox"/>



Annexure B

Letter of HOMOLOGATION REJECTED



Your ref.:

Our ref.: **Homologation of RPD -
HOMOLOGATION
REJECTED.DOC**

Enquiries:



Technical file No.:

Date: 29/10/2010

Page: 1 of 1

«Company»
Attention: «Title» «First» «Last»
«Address»
«City»
«ZipPostal_Code»
«Country»

Dear Sir/Madam

Homologation of RPD: HOMOLOGATION REJECTED

You are hereby notified that the application for the homologation of the following type of respiratory protective device (RPD) has been rejected:

RPD type: [Manufacturer's name or trade mark] [Model designation] [Standard designation in accordance with relevant product specification standard]

Please refer to the following NRCS Inspection Report for the type-examination results:

NRCS Inspection Report No. XXXX

The NRCS Inspection Report must be collected at the following premises:

NRCS Head Office
SABS Campus
1 Dr. Lategan Road
Groenkloof
Pretoria

The NRCS Inspection Report will be disposed of if not collected within six (6) months from the date of this notification.

Yours faithfully,

T. Magolego (Mrs.)
MANAGER: APPROVALS
NRCS Chemicals, Mechanical & Materials Division

NRCS Chemicals, Mechanical & Materials Division
SABS Campus 1 Dr. Lategan Road Groenkloof Pretoria
Private Bag X25 BROOKLYN 0075
Tel. +27 12 428-6377 • Fax. +27 12 428-6513
www.nrcs.org.za

Doc No: 5337 Homologation of RPD

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15 Revision particulars

Revision No.	Date of implementation	Nature of revision
-	-	-

No.:

Date: 16/03/2011

Page: 1 of 6

1. PRODUCT INFORMATION

Manufacturer's trademark: _____

Type-identifying marking: _____

Designation: _____

2. GENERAL

2.1 Inspection method

Type-examination of a type of respiratory protective device (RPD) in accordance with Divisional Procedure No. 5337 E004.

Examination of a RPD sample in accordance with Divisional Procedure No. 5337 E023.

Sales Permit application in accordance with Divisional Procedure No. REG 003.

2.2 Items required

	Included		Acceptable	
	Yes	No	Yes	No
<u>Application for homologation</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Applicant has submitted the items as communicated to him by means of NRCS form No. VC8072-A.1.				

Remarks:

3. TECHNICAL FILE

No.: _____

Inspection date(s): _____

3.1 Completeness and correctness of technical file

	Included		Acceptable	
	Yes	No	Yes	No
B.1 Application form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Application for homologation</u>				
NRCS form No. VC8072-A.3 or any other document that satisfies the requirements of the aforementioned document.				
<i>Note: The applicant shall be the manufacturer or importer of the type of RPD. The manufacturer or importer shall be established within the Republic of South Africa.</i>				
<u>Application for a Sales Permit</u>				
Application form as set out in Divisional Procedure No. REG 003.				
Remarks:				
B.2 Technical specifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A technical description supported by technical drawings of the type of RPD, indicating the following as a minimum:				
a) All component parts.				
b) Description of each component part.				
c) Material(s) used in each component part.				
d) Methods of assembly.				
e) Colour of the type of RPD.				
f) Marking of the type of RPD as required by the relevant South African National Standard.				
<i>Note 1: The technical drawings shall be to scale.</i>				
<i>Note 2: Photographic evidence may be included with the technical file in order to support the technical specifications.</i>				
Remarks:				
B.3 Packaging	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Details of the marking of the packaging for the type of RPD as required by the relevant South African National Standard.				
Remarks:				
B.4 Information notice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Instructions for use/information supplied by the manufacturer for the type of RPD as required by the relevant South African National Standard.				
Remarks:				

Included		Acceptable	
Yes	No	Yes	No

B.5 Proof of compliance

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

Copies of test reports demonstrating compliance with an appropriate South African National Standard for RPDs, ensuring that all component parts and facepiece sizes (when applicable) have been covered.

Note 1: Only test reports from a testing authority that has been accredited in accordance with the latest edition of SANS 17025 by a signatory to the International Laboratory Accreditation Co-Operation's Mutual Recognition Agreement shall be accepted. No approval certificates shall be accepted.

Note 2: Test reports shall satisfy the requirements of the latest edition of SANS 17025. See NRCS form No. VC8072-A.5 for guidance.

Testing authority: _____ **Test Report No.:** _____

Testing authority: _____ **Test Report No.:** _____

Testing authority: _____ **Test Report No.:** _____

Remarks:

B.6 Quality assurance

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

Copy of a certificate from a certification authority certifying that the quality management system applied by the manufacturer or importer satisfies the requirements of the latest issue of SANS 9001.

Note 1: Only certification certificates from a certification authority that has been accredited in accordance with SANS 17021 by an organization that is part of the International Accreditation Forum Mutual Recognition Agreement shall be acceptable.

Note 2: Certification certificates shall satisfy the requirements of SANS 17021 and shall still be valid on the date of receipt.

Certification authority: _____ **Certification Certificate No.:** _____

Remarks:

B.7 Other

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

Any other materials that the applicant has included in the technical file and that will be considered for the type-examination process.

Remarks:

3.2 Suitability of technical file with respect to demonstrating compliance with SABS EN XXX:XXXX

The technical file was inspected for compliance with SABS EN XXX:XXXX.

This part of the inspection report should be read in conjunction with SABS EN XXX:XXXX.

SABS EN XXX:XXXX Requirements	EXAMINATION OF TECHNICAL FILE	ACCEPTABLE	
		Yes	No
5 Requirements		<input type="checkbox"/>	<input type="checkbox"/>
7 Instructions for use			
7.1		<input type="checkbox"/>	<input type="checkbox"/>
7.2		<input type="checkbox"/>	<input type="checkbox"/>

SABS EN XXX:XXXX Requirements	EXAMINATION OF TECHNICAL FILE	ACCEPTABLE	
		Yes	No
7.3		<input type="checkbox"/>	<input type="checkbox"/>
7.4		<input type="checkbox"/>	<input type="checkbox"/>
7.5		<input type="checkbox"/>	<input type="checkbox"/>
7.6		<input type="checkbox"/>	<input type="checkbox"/>
7.7		<input type="checkbox"/>	<input type="checkbox"/>
7.8		<input type="checkbox"/>	<input type="checkbox"/>
8	Marking		
8.1		<input type="checkbox"/>	<input type="checkbox"/>
8.2		<input type="checkbox"/>	<input type="checkbox"/>
8.3		<input type="checkbox"/>	<input type="checkbox"/>
8.4		<input type="checkbox"/>	<input type="checkbox"/>
8.5		<input type="checkbox"/>	<input type="checkbox"/>
8.6		<input type="checkbox"/>	<input type="checkbox"/>
8.7		<input type="checkbox"/>	<input type="checkbox"/>
8.8		<input type="checkbox"/>	<input type="checkbox"/>
8.9		<input type="checkbox"/>	<input type="checkbox"/>
8.10		<input type="checkbox"/>	<input type="checkbox"/>

3.3 Suitability of technical file with respect to demonstrating compliance with SANS 9001:2000

ACCEPTABLE:

Yes No

The type of RPD is imported or manufactured under a quality management system applied by the manufacturer or importer that satisfies the requirements of SANS 9001:2000

Remarks:

4. REFERENCE SAMPLE

No.:

Inspection date(s):

.....

.....

4.1 Verification of production in accordance with technical file:

		Acceptable	
		Yes	No
B.1	Application form	<input type="checkbox"/>	<input type="checkbox"/>
Homogeneity of the reference sample with the product information as contained in the application form.			
<i>Remarks:</i>			
B.2	Technical specifications	<input type="checkbox"/>	<input type="checkbox"/>
Homogeneity of the reference sample with the technical specifications.			
<i>Remarks:</i>			
B.3	Packaging	<input type="checkbox"/>	<input type="checkbox"/>
Homogeneity of the reference sample with the marking of the packaging for the type of RPD as required by the relevant South African National Standard.			
<i>Remarks:</i>			
B.4	Information notice	<input type="checkbox"/>	<input type="checkbox"/>
Homogeneity of the reference sample with the instructions for use/information supplied by the manufacturer for the type of RPD as required by the relevant South African National Standard.			
<i>Remarks:</i>			
B.5	Proof of compliance	<input type="checkbox"/>	<input type="checkbox"/>
Homogeneity of the reference sample with the information as contained in the test report(s) or approval certificate(s).			
<i>Remarks:</i>			
B.7	Other	<input type="checkbox"/>	<input type="checkbox"/>
Homogeneity of the reference sample with any other materials that the applicant has included in the technical file and that were considered for the type-examination process.			
<i>Remarks:</i>			

5. REMARKS

-

6. CONCLUSION

		Yes	No
Technical file complete and correct:		<input type="checkbox"/>	<input type="checkbox"/>
Technical file satisfied the requirements of SABS EN XXX:XXXX:		<input type="checkbox"/>	<input type="checkbox"/>
Reference sample manufactured in accordance with the technical file:		<input type="checkbox"/>	<input type="checkbox"/>
Quality management system satisfied the requirements of SANS 9001:2000:		<input type="checkbox"/>	<input type="checkbox"/>
<i>Remarks:</i>			

Yes No

Type of RPD recommended for homologation in accordance with SANS 10338:2009:

Type of RPD recommended for a Sales Permit in terms of Section 14(4) of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008):

Remarks:

MANAGER: APPROVALS
NRCS CMM DIVISION

INSPECTOR
NRCS CMM DIVISION

---oOo---

6. **Manufacturer**

Name:

Address:

7. **Reference documents**

The following documents, bearing the type approval number shown below, are attached to this homologation certificate:

- **Drawings, diagrams, plans and photographs of the type of respiratory protective device;**
- **Details of the marking of the type of respiratory protective device;**
- **Details of the marking of the packaging for the type of respiratory protective device;**
- **Information for users for the type of respiratory protective device.**

---oOo---

6. **Manufacturer**

Name:

Address:

7. **Reference documents**

The following documents, bearing the type approval number shown below, are attached to this homologation certificate:

-

---oOo---

Type approval No.	Description
1	Type of regulatory protective device
2	South African National Standard applicable to type of regulatory protective device
3	Terms and conditions of issue
4	Homologation certificate as applicable only to the type of regulatory protective device as identified in 1
5	The applicant shall ensure the existence of a quality management system of the manufacturer's production facility that conforms to the requirements of the South African National Standard SANS 9001
6	The manufacturer shall be able to provide to the type of regulatory protective device used, its design and manufacturing specifications and drawings in accordance with the requirements of the South African National Standard SANS 9001
7	The manufacturer shall be able to provide to the type of regulatory protective device used, its design and manufacturing specifications and drawings in accordance with the requirements of the South African National Standard SANS 9001
8	Homologation certificate



Inspector
NRCS CMM Division

Manager Approvals
NRCS CMM Division



6. **Manufacturer**

Name:

Address:

7. **Reference documents**

The following documents, bearing the type approval number shown below, are available on request:

-

---000---

HOMOLOGATION WITHDRAWN

