



DEVELOPMENT AND APPROVAL PROCESS FOR TECHNICAL REGULATIONS

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1. PURPOSE

- 1.1. The purpose of this document is to describe the process for the development and approval of any new Technical Regulations for recommendation for publication by the Minister.
- 1.2. It also to describe the process for the amendment, or withdrawal of any existing Technical Regulation, for recommendation for publication by the Minister.

2. SCOPE

This document is intended to cover all requested for new Technical Regulations, or amendments to, or withdrawal of, an existing, Technical Regulation, administered by the NRCS.

3. NORMATIVE AND INFORMATIVE REFERENCES

3.1. NORMATIVE

Procedure – RR&D 007 - Risk Assessment procedure

Procedure – RR&D 008 - Impact Assessment procedure

Procedure – RR&D 009 - Project Feasibility procedure

Procedure – RR&D 010 - Project Proposal Preparation procedure

Procedure – RR&D 011 - Submission of Technical Regulations for approval

Procedure – RR&D 012 – Periodic review of Compulsory Specifications

3.2. INFORMATIVE

None

4. DEFINITIONS

- 4.1. **Project Manager:** A person appointed by the Manager of the RR&D Division to manage the process on requested new Technical Regulations, or amendment or withdrawal of an existing one.
- 4.2. **Technical Regulation (TR)/Compulsory Specification (VC):** A document that specifies technical requirements that are made mandatory by legislation in terms of any Act of parliament or regulations to any Act. Such Technical Regulation may refer to requirements in an international or national standard, thereby making those mandatory.

4.3. Minister: The Minister of the Department of Trade and Industry**5. ACRONYMS**

5.1 CEO	Chief Executive Officer of NRCS
5.2 IA	Impact Assessment
5.3 PAC	Project Approvals Committee.
5.4 RR&D	Regulatory Research and Development Business Unit of NRCS.
5.5 RA	Risk Assessment
5.6 The dti	The Department of Trade and Industry.
5.7 TWG	Technical Working Group
5.8 TR	Technical regulation (Also refers to Compulsory Specification or VC)
5.9 TC	Technical Committee of NRCS.

6. GENERAL RULES

- 6.1.** Any person or organisation may submit a request that any Technical Regulation, to be administered by NRCS, be introduced, or an existing one, be amended or withdrawn. The NRCS can also proactively determine safety-critical products or services in the scope of NRCS's regulatory work.
- 6.2.** All requests or identified products/services shall be assessed by the relevant Technical Specialist for feasibility (in accordance with RRD 009) by presenting the feasibility report at the Projects Approval Committee (PAC) of the RR&D. A project proposal (in accordance with RRD 010) will also be assessed at this stage for feasible projects.
- 6.3.** The outcome of the feasibility report shall be submitted, in writing, to the CEO with the necessary motivation for it, to either:
- recommend registration of VC/TR project;
 - request a South African National Standard (SANS) or any international standard if SANS is not available;
 - recommend official research;
 - list on the regulatory gap matrix (allocating relevant department/regulator); or
 - submit a not feasible report.

NOTE: One or more of these options can be selected to run concurrently. Where applicable, the use of section 13(1)(c) of the NRCS Act and 22 (2)(c) of the LM Act will be explored.

- 6.4** In the case of 6.3 (e) the CEO shall inform the originator of the request in writing of the decision of the NRCS not to proceed with the request.
- 6.5** All feasible projects with their project proposals shall be registered at CEO's office and forwarded to the head of RR&D.

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- 6.6** Risk assessments and impact assessments shall be conducted on all feasible projects for new Technical Regulations.
- 6.7** Consultation with affected stakeholders shall be done on any requested new, or amendments to, or withdrawal of, existing Technical Regulations.
- 6.8** A decision on the introduction of any new Technical Regulation will be based on feasibility, risk assessment and impact assessment reports.
- 6.9** Reports produced in the course of work shall be reviewed for quality and accuracy and approved by the PAC at periodic intervals outlined in the procedure (outlined in paragraph 7).

7. THE PROCEDURE

7.1. THE REGISTRATION OF THE REQUEST TO DEVELOP, AMEND OR WITHDRAW A TECHNICAL REGULATION

- 7.1.1.** Any feasible registered projects (in paragraph 6.5) shall be allocated the next consecutive request number from the register.
- 7.1.2.** A copy of the request shall be kept at the CEO's office, and the original forwarded to the Head of the RR&D for processing.
- 7.1.3.** On receipt of the official project registration (in paragraph 6.5) the head of RR&D shall obtain the next available project number from the RR&D Project Register and file accordingly.

7.2 REGULATORY RISK ASSESSMENT

7.2.1 The Project Manager shall either:

- a) Conduct RA and IA for all new TRs or proposed withdrawals of existing TRs and unless indicated as unnecessary in the project proposal for stated reasons that were accepted by the PAC, OR
- b) Proceed to the drafting stage for amended TR from **(paragraph 7.3)**, unless the project proposal indicates the necessity for RA for stated reasons that are acceptable to the PAC; in which case the Project Manager will continue the in the same manner stated in sub –paragraph (a) above.

7.2.2 If it is concluded by the PAC that the project should proceed in accordance with **paragraph 7.2.1 (a)**, the Project Manager shall:

- a) Set up a stakeholder consultation meeting, to which all known available affected stakeholders identified in the Project Plan are invited.
- b) Introduce the request to the stakeholder and proceed to conduct the RA in accordance with procedure **RR&D 007**.
- c) At the meeting, set up a Technical Working Group representative (volunteers) of all sectors of affected stakeholder to work with the Project Manager on the drafting and impact assessment stages of the project.
- d) Record the minutes of the meeting accordingly.

7.2.3 After the stakeholders' meeting, the Project Manager shall:

- a) Ensure that minutes of the meeting (in **paragraphs 7.2.1(d)**) are completed and circulated to stakeholders that attended the meeting.
- b) Compile the draft RA Report, based on researched items and inputs from the meeting and submit it to the next scheduled meeting of the PAC for review and approval.

7.2.4 At its next scheduled meeting, the PAC shall review the RA Report and decide if the identified risks are of such a magnitude, that the project should be continued with or not.

If any items in project reports require correction, amendment or addition, as the case maybe, these must be done and then re-submitted to the PAC until approval is granted

7.2.5 If the PAC concludes in accordance with **paragraph 7.2.4**, that the project should proceed to the next phase, it shall move on wards in accordance with **paragraph 7.3**.

7.2.6 If it the PAC concludes **NOT** to continue with the project, the Head of RR&D and the project Manager shall:

- a) Prepare a submission for review of the proposal to close the project by the NRCS TC according to **RR&D 011** *Submission of Technical Regulations for approval*.
- b) Once reviewed by the NRCS TC and a recommendation is made to the CEO to close

the project, prepare and submit a report and request for closure to the CEO indicating that the request will not be further processed and provide reasons thereof, and

- c) Once approved by the CEO, inform the originator of the request in writing of the decision of the NRCS to close the project and provide the reasons thereof.

7.2.7 The project shall be considered closed once the letter in **paragraph 7.2.6 (c)** letter is sent to the originator of the request.

7.3 THE REGULATORY IMPACT ASSESSMENT

7.3.1 If it is decided to continue with the project (**in paragraph 7.2.5**) the Project Manager shall:

- a) Prepare an initial draft Technical Regulation.
- b) Request the responsible NRCS Line function to prepare the costing (new, or additional) to regulate and the draft levy schedule.
- c) Invite the stakeholders to attend an Impact Assessment (IA) Meeting and circulate a copy of the draft to all invitees and NRCS Managers.
- d) Conduct impact assessment at the meeting, in accordance with procedure **RR&D 008**.
- e) Record the minutes of the meeting accordingly.

7.3.2 After the stakeholders' meeting, the Project Manager shall:

- a) Compile the draft IA Report, based on researched items and inputs from the meeting.
- b) Ensure that minutes of the meeting and the draft IA report (**in paragraphs 7.3.1 (e)**) are completed and circulated to stakeholders that attended the meeting.

7.3.3 If the IA meeting concludes that it is not feasible to continue with the request, the Project Manager/TS shall submit the draft IA Report to the next scheduled meeting of the PAC for review and approval.

7.3.4 At its next scheduled meeting, the PAC shall review the RA Report and decide if the identified regulatory impacts are of such a magnitude, that the project should be continued with or not.

NOTE: If any items in project reports require correction, amendment or addition, as the case maybe, these must be done and then re-submitted to the PAC until approval is granted

7.3.5 If it the PAC also concludes **NOT** to continue with the project (in paragraph **7.3.3**), the Project Manager shall through the Head of RR&D:

- a) Prepare a submission for review of the proposal to close the project by the NRCS TC according to **RR&D 011**, *Submission of Technical Regulations for approval*.
- b) Once reviewed by the NRCS TC and a recommendation is made to the CEO to close the project, prepare and submit a report and request for closure to the CEO indicating that the request will not be further processed and provide reasons thereof; and
- c) Once approved by the CEO, inform the originator of the request in writing of the decision of the NRCS to close the project and provide the reasons thereof.

7.3.6 The project shall be considered closed once the letter in paragraph **7.3.4 (c)** letter is sent to the originator of the request.

7.3.7 If the TWG meeting (Paragraph **7.3.1**) concludes to continue with the proposed new Technical Regulation or an amendment to an existing one (Paragraph **7.2.1**), the Project Manager shall:

- a) Incorporate comments from TWG, including the proposed levy schedule and other applicable fees in the draft IA Report
- b) Finalise the draft of the proposed Technical Regulation and taking into consideration comments submitted by stakeholders or made during consultation meetings and in the case of a new compulsory specification, allocate a unique identification number to it from the register, e.g.: VC XXXX.
- c) Set up a final stakeholder consultation meeting, to which all known available affected stakeholders are invited.
- d) Circulate the draft TR and IA report to the invited stakeholders.

7.3.8 The full stakeholders meeting (paragraph **7.3.5 (c)**) shall be conducted in accordance with RR&D 008 - Impact Assessment procedure, which includes at least the following:

- a) Discuss the proposed Technical Regulation (new or amended), the draft IA report including proposed levy schedule and other fees, as applicable, and invite comments.
- b) Identify and assess the meeting on any anticipated impacts that stakeholders due to the proposed Technical Regulation or levies, and provide rationale as to the requirements therein.
- c) Consider any comments on the draft TR and IA Report and incorporate the comments accordingly.
- d) Record the minutes of the meeting.

7.3.9 After the stakeholders' meeting, the Project Manager shall:

- a) Finalise levy schedule (and other fees, if applicable), and prepare a submission to the Finance for Gazetting in the Levy Schedule in the case of new TRs or an update of existing applicable fees.
- b) Compile the final draft IA Report, based on researched items and inputs from the meeting and submit the draft TR, IA and any other associated documentation to the PAC for review and approval. Complete the final draft of the Technical Regulation, the IA report and any other associated documents and submit to PAC for approval.
- c) Ensure that minutes of the meeting are completed and circulated to stakeholders that attended the meeting.

7.3.10 If it the PAC also concludes **NOT** to continue with the project, the Project Manager shall through the Head of RR&D:

- a) Prepare a submission for review of the proposal to close the project by the NRCS TC according to **RR&D 011**.
- b) Once reviewed by the NRCS TC and a recommendation is made to the CEO to close the project, prepare and submit a report and request for closure to the CEO indicating that the request will not be further processed and provide reasons thereof; and
- c) Once approved by the CEO, inform the originator of the request in writing of the decision of the NRCS to close the project and provide the reasons thereof.

7.3.11 The project shall be **considered closed** once the letter in paragraph **7.3.6 (c)** letter is sent to the originator of the request.

7.3.12 If the PAC concludes that the project should proceed to the next phase, it shall move on wards in accordance with paragraph **7.4**.

7.4 SUBMISSION OF THE PROPOSAL TO DEVELOP, AMEND OR WITHDRAW THE TR TO THE TECHNICAL COMMITTEE

7.4.1 Once the proposed Technical Regulation is approved by PAC the Project Manager shall, through the office of the Head of RR&D:

- a) Prepare a submission for NRCS TC approval according to RRD011, *Submission of Technical Regulations for approval*.
- b) Prepare and make a submission to NRCS TC for review and for recommendation to the CEO to approve the project for submission to the dti for the Minister to

publish the proposed Technical Regulation for comment and draft a notification to the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) on the online system.

7.4.2 Once recommended by the NRCS TC, the proposed Technical Regulation shall be submitted to the CEO for approval; and if approved, thereafter submitted to the dti in accordance with paragraph 7.5.

7.4.3 If for any reason the proposal is rejected, the recommendations of the NRCS TC will be taken in to consideration and implemented accordingly by the Head of RR & D and the project Manager until the matter is concluded.

IMPORTANT: Any comments by NRCS TC shall be considered and re-submitted if necessary by the Project Manager until resolved.

7.4.4 If it the NRCS TC also recommends **NOT** to continue with the project:

- a) Prepare and submit a report to the CEO indicating the recommendation of the NRCS TC and provide reasons for the decision;
- b) Once reviewed by the NRCS TC and a recommendation is made to the CEO to close the project, prepare and submit a report and request for closure to the CEO indicating that the request will not be further processed and provide reasons thereof; and
- c) Once approved by the CEO, inform the originator of the request in writing of the decision of the NRCS to close the project and provide the reasons thereof

7.4.5 The project shall be considered closed once the letter in paragraph 7.4.4 (c) letter is sent to the originator of the request.

7.5 SUBMISSION TO THE DTI

7.5.1 Once the proposed Technical Regulation is approved by the NRCS TC, the Project Manager shall, through the office of the Head of RR&D:

- a) Prepare a formal submission to the dti requesting approval and publication in the Government Gazette in accordance with procedure RR&D 011.
- b) At the time of submitting to the dti, prepare and submit the WTO notice form and submit it to the WTO enquiry point.

7.6 COMMENTS REVIEW

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- 7.6.1** Once the dti has published the draft TR for comments and no comments or substantial comments (have material effect on the draft TR) are received from the public, the Project Manager shall proceed according to paragraph 7.6.8.
- 7.6.2** If substantial comments are received after publication within the specified time period, the project Manager shall set up an NRCS Comments Review Meeting with affected stakeholders and the TWG shall be invited to consider and resolve the issues raised. If comments received are not substantial, the project Manager shall set up a meeting with affected stakeholders only or draft a response to the comments.
- 7.6.3** The Review Committee (in paragraph 7.6.2) shall review all comments to the proposed technical regulation and decide if any changes need to be made to the proposed Technical Regulation, or not.
- 7.6.4** Once comments review resolutions have been made, the Project Manager shall:
- a) Revise the proposed Technical Regulation (as gazetted) to reflect the changes, if needed agreed (in paragraph 7.6.3) into the final Technical Regulation.
 - b) Ensure minutes of the Comments Review Meeting are completed and circulated to those who submitted comments and the Review Committee members.
- 7.6.5** Submit the comment review report to the next scheduled PAC meeting for review and approval.
- a) If significant changes are made to the technical regulation, it shall be re-gazetted for comment.
 - b) If re-gazetted for further comments carry out the procedure from paragraph 7.4.
- 7.6.6** Prepare a formal submission to NRCS CEO and the dti, requesting approval and recommendation for publication of the Technical Regulation as a final notice in the Government Gazette in accordance with procedure RR&D 011.

8 RECORDS

All records related to the CSP350 process shall be filed by the project manager as per NRCS RRD file plan.

9 FORMS

Online WTO notification form

10 REPLACEMENT AND WITHDRAWAL

This document replaces CSP 350, Rev.01: Development and Approval of Technical Regulations dated 2010-10-05.

ANNEX A

DEVELOPMENT AND APPROVAL OF TECHNICAL REGULATIONS

