NRCS – RISK BASED APPROACH POLICY

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1. Policy Statement

The NRCS shall develop, implement, maintain, and continuously improve on a Risk Based Approach (RBA) in the core value chain market surveillance and regulatory supervision activities. The RBA shall be implemented in all approvals (including type approvals and homologation) and market surveillance inspections across all regulatory functions of the organisation.

The RBA is anchored on the following levers:

a) Takes into account the probability of failure and the consequence of failure
b) The higher the risk, the more the degree of intervention; the lower the risk, the less the degree of intervention
c) Evidence based risk rating

2. Objectives of RBA

The objectives of the RBA of the NRCS include the following:

2.1 Optimising the costs and benefits of the allocation of resources by deploying a regulatory framework which is more targeted, with a focus on the main risks and objectives.
2.2 Raising the efficiency and effectiveness of executing the regulatory mandate of the organisation by concentrating on what needs to be done.
2.3 Standardising and improving on business processes across the organisation.
2.4 Minimising the occurrence of non-compliances by adequately intervening in the high risk scenarios.
2.5 Levelling the playing field by promoting transparency, consistency, and fairness in the organisation's enforcement and market surveillance program.
2.6 Recognising and promoting good compliance behaviour amongst the regulated entities.
2.7 Enablement of informed decision making that will increase confidence in the organisation's programs.
2.8 Creating and sustaining a culture of continuous improvement that keeps abreast of best regulatory practice.

3. References

ISO 31000 – Risk Management – Principles and Guidelines for Implementation
Internal Policy Document relating to the issuing of Letters of Authority
NRCS Strategy 2018/19 – 2022/23

4. Definitions

Risk – the effect of uncertainty on objectives
Risk appetite – the amount of risk that the organisation is willing to accept

5. The NRCS Risk Based Approach Model

5.1 Risk rating and weighting

The NRCS RBA model is based on evaluating the risk according to three main variables; the company risk (CR), the product risk (PR), and the country of origin risk (COOR). The risk rating (RR) is calculated as the summation of the weighted risks of each of the above variables according to the relationships given in Equations 1 & 2.

$$RR = W_{pr}*PR + W_{cr}*CR + W_{coor}*COOR \quad \text{Equation 1}$$

Where

W_{pr} = weighting of product risk
W_{cr} = weighting of company risk
W_{coor} = weighting of country of origin risk

$$1 = W_{pr} + W_{cr} + W_{coor} \quad \text{Equation 2}$$

The following values, in Table 1, shall apply for each of the business units of the NRCS:

Table 1: Weightings of each risk variable per business unit

Business Unit	W_{pr}	W_{cr}	W_{coor}
Electrotechnical	0.6	0.4	0
CMM	0.6	0.4	0
Automotive	0.6	0.4	0
Legal Metrology	0.6	0.4	0

FAI	X	X	X

5.2 Scoring

5.2.1 Risk factors

A 5*5 matrix shall be used for calculating the risk ratings i.e. product risk, company risk, and country of origin risk; using values of factor ratings as shown in Table 2. The risk rating is the product of the probability/likelihood of occurrence by the impact/severity/consequence, that is:

Risk rating = probability * severity Equation 3

Table 2: Likelihood/probability and impact/severity/consequence guide

Factor rating	Likelihood/probability	Impact/severity/consequence
5	Almost certain	Catastrophic
4	Likely	Critical
3	Possible	Major
2	Unlikely	Moderate
1	Remote	Minimal

From Equation 3 and the factor ratings given in Table 2, it follows that:

Maximum risk rating = 5*5 = 25, and

Minimum risk rating = 1*1 = 1

5.2.2 Compliance history as a determinant of the probability factor

The RBA model shall be evidence based, using compliance history data over a given period. The compliance history of the company, product, and/or country of origin is used to determine the likelihood/probability factor.
The compliance history data over a period of at least 12 months is gathered and correlated to the likelihood factors as shown in Table 3. Therefore, it follows that a given compliance rate depicts a certain level of the likelihood of occurrence as represented by the likelihood factor.

Table 3: Likelihood and compliance rate

Likelihood factor	Likelihood description	Compliance rate[1] (%)
5	Almost certain	X_1
4	Likely	X_2
3	Possible	X_3
2	Unlikely	X_4
1	Remote	X_5

Notes 1 Compliance rate = no. of non-compliances / no of approvals/inspections conducted on the company/product/country of origin in a given period

Each business unit must specify the compliance rate ranges ($X_1 - X_5$) that correspond to each of the likelihood factors in Table 3.

5.3 Risk classification

The various risk ratings are classified into at least three categories

a) Low risk: 1-4
b) Medium risk: >4-12
c) High risk: >12-25

The risk categories are shown in Fig 1 below. The low risk ratings are colour coded in green; the medium risk ratings are colour coded in yellow; and the high risk ratings are colour coded in red. The risk classification in Fig 1 is set out in accordance with the organisation's risk appetite that may exist from time to time. The degree of regulatory intervention will vary according to the risk classification.

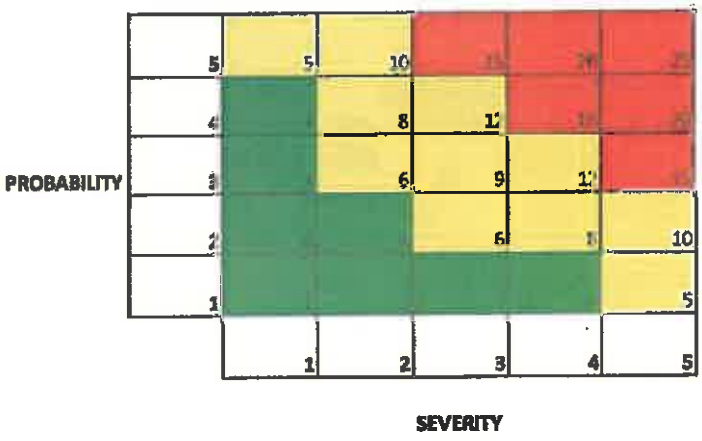

Fig 1: Risk rating classification guide

6. Guideline for the implementation of RBA

The RBA process is illustrated by the schematic in Fig 2.

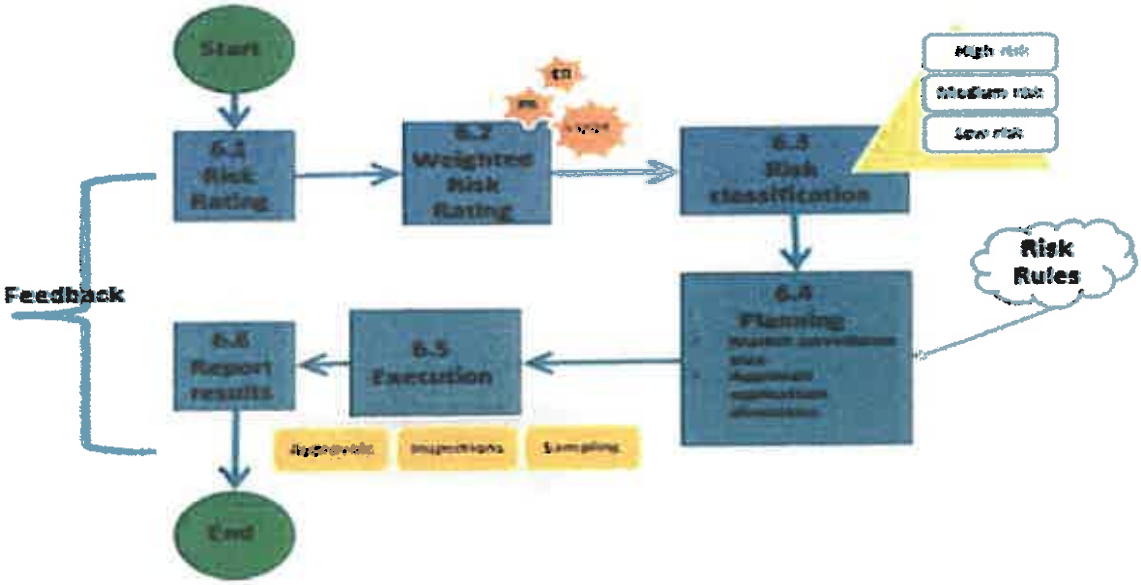

Fig 2: RBA process schematic

6.1 Determine the risk rating for each of the variables; namely product risk, company risk, and country of origin risk in accordance with Equation 3, by multiplying the likelihood and the severity. The risk rating is calculated manually or automatically by an ICT system

6.1.1 For manual calculation, the severity and probability factors are determined from Table 2, using the data collected for a minimum period of 12 months. The risk ratings and classifications are entered into a risk register as shown in Annexure 1. The manual risk register shall be updated/ reviewed at six months intervals.

6.1.2 The ICT system generated risk ratings are calculated on an ongoing basis by the computer system in accordance with the combinations of product risk, country of origin risk, and company risk at a specific period

6.2 Determine the weighted average risk rating by combining the product risk, company risk, and country of origin risk in accordance with the relationships given in Equations 1 & 2, using the weightings given in Table 1.

6.3 Classify or rank the resultant weighted average risk rating into any of the three risk categories of low risk, medium risk, and high risk in accordance with the risk appetite set out in Fig 1. The results are entered into the risk register, Annexure 1, or generated by the ICT system.

6.4 Apply the applicable risk rules to each scenario in accordance with the risk category or classification for the purposes of planning the executing of the regulatory activity:

6.4.1 For approvals the risk classification will determine the turnaround time, amongst other things

6.4.2 For surveillance inspections the risk classification will determine, amongst other things, what is to be inspected, where the inspection will be conducted, the type of inspection to be conducted, inspection frequency, and the sampling frequency.

6.5 Conduct or execute the regulatory activity in accordance with the business unit procedures

6.6 The results from the regulatory activity shall be recorded and codified in a database. The resultant database will serve as input for the continuous improvement of the estimates of the risk profiles.

7. Risk rules

7.1 The following generic rules shall apply :

7.1.1 Renewal approval applications shall be classified as low risk provided

a) the application was submitted at least 3 months before the expiry of the existing approval,
b) The application meets the requirements of the compulsory specification/technical regulation,
c) and the same conditions under which the last approval was granted still exist.

If the aforementioned conditions are not met, the application is treated as a new application.

7.1.2 Special routing or queuing rules, with the effect of expediting the processing of applications, shall be applied for the following categories of approval applications:

a) locally manufactured products,
b) products destined for National Key Points, and
c) National Special or Priority Projects.

7.1.3 Where findings have been raised against an applicant, the application shall be cancelled 30 days after of communicating the findings, in the case where the applicant has not adequately responded to address the findings.

7.1.4 The target turnaround times for approvals shall be as follows:

Low risk: within 75 calendar days
Medium risk: within 90 calendar days
High risk: within 120 calendar days

7.1.5 Compulsory specifications or technical regulations that have been enforced for a period that is less than or equal to two years are automatically considered as high risk

7.1.6 The higher the risk rating, the more the degree of regulatory intervention; the lower the risk rating, the less the degree of regulatory intervention

7.1.7 At the ports of entry, embargo releases may be granted for low risk scenarios, where the applicant for approvals has submitted their application(s) in time, the delay was due to the NRCS, and the target turnaround times have been exceeded.

7.2 Each business unit shall develop further risk rules that may be applicable in its regulatory scope to further clarify the implementation of the RBA

7.3 In all cases, the risk rules should not be a trade barrier, with the unintended consequence of hindering the flow of trade for compliant regulated entities. The RBA shall not fail to respond to dynamic market situations such as international alerts, disease outbreaks and/or product recalls that may occur from time to time. In such cases management shall exercise managerial options through a transparent process.