Recommendation S

That: *Authorities plan surveillance activities on the basis of the evaluation of the non-compliance risk of products/businesses within their jurisdiction.*

That: *The evaluation of the non-compliance risk should reflect:*

- *How dangerous a certain product/business entity is when it is non-compliant to standards,*
- *What is the probability that a non-compliant product of this type is present on the market.*

2

WORKSAFE NEW ZEALAND

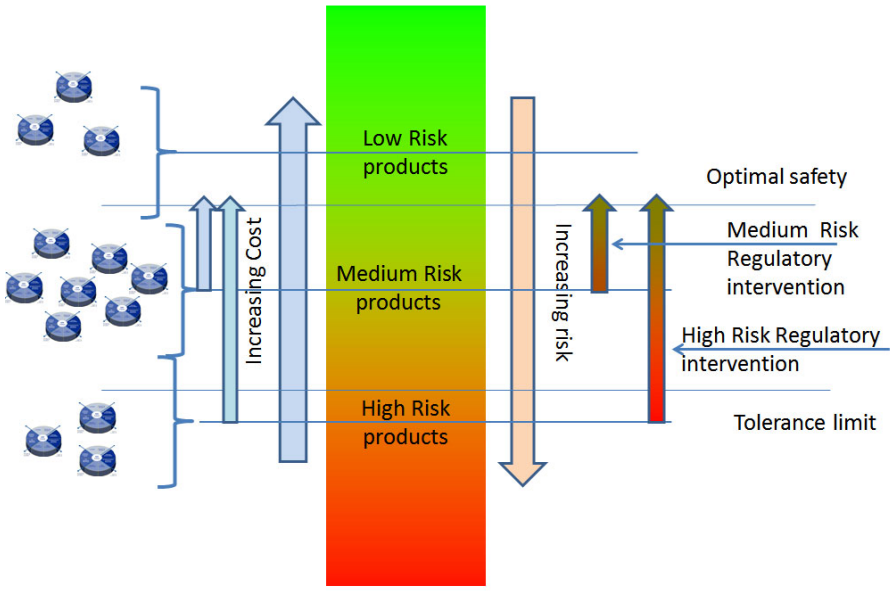
What is Risk?

Risk can be reduced by design or by Regulatory intervention, both pre-market and post-market

Regulatory Intervention

The purpose of Regulatory intervention is to compensate for market failures and bring compliance into tolerable levels

In a customs context this might be to decide whether to inspect a shipment or accept the accuracy of documentation



5

WORKSAFE NEW ZEALAND

Role of a Regulator

All jurisdictions have the right to regulate for the safety and health of their population (WTO) but are expected to regulate in accordance with risk management principles, and apply wherever possible international Standards for both the attainment of safety and the types of regulatory systems applied.

This places a discipline on enforcement activities applied both pre-market and post-market, including those applied at the border.

In the case of the electrical and electronic equipment (EEE) – the role is to ensure that the society gets to benefit from the use of electrical energy at a tolerable risk.

6

WORKSAFE NEW ZEALAND

Three risk categories

From consultations with experts on the safety of electrical equipment we concluded that there was not enough certainty to establish more than three risk categories:

- **The highest perceived to be needed,**
- **The lowest perceived to be tolerable,**
- **A middle ground that addresses uncertainty between the other two.**

The New Zealand Electrical Safety Regulatory Risk Engine:

The NZ risk engine is an advanced model of a predictive risk assessment tool used for Regulatory applications operated by the NZ electrical equipment safety regulating agency within WorkSafe NZ

Origin of the Engine

The development of NZ's analytical risk assessment tool began in 2006 in response to an ASEAN desire to create a harmonised regulatory system for its members

The design was based on the consideration of more than 10 years of product non-compliance incidents in NZ and Australia

9

The Challenge

To create a risk assessment tool (Risk Engine) that can predict the level of Risk that any type of electrical equipment creates to enable an appropriate level of Regulatory intervention to be applied to "correct" the marketplace risk within a tolerable level

To avoid the lag of a system based on incidents

10

Quantitative versus Qualitative

The quantitative method requires significant data that is both accurate and timely.

The qualitative method is generally course and not consistent, and depends on the judgement of the accessors.

The NZ risk engine applies a semi-quantitative methodology designed to use historically derived probability causal based data and technical factors of the potential degree of hazards.

The engine focusses on the drivers and effects of non-compliance, not the probability of compliance.

We focus on the comparative assessment and not on actual values

The goal being to separate the products into different groupings

Qualitative

Compliance cost matched against risk

Certification Components	Risk		
	Low	Medium	High
Safety certificate	Must	Must	Must
Certificate of compliance		Must	Must
Record of inspection (e) Witness testing (g)			Must
Lodge on high risk register			Must

NZ Risk engine

The NZ risk assessment system, while built on the fundamental risk based principle of assessing both probability and consequence, takes an approach which:

- **Applies causal factors for assessing probability,**
- **Uses contributors to injuries and damage to assess consequences.**

The system is designed to evaluate the risk of non-compliance with established benchmarks, such as Standards or Regulations.

The system does not establish an actual risk value, but looks at differential ratings.

NZ Risk engine

The system maintains the visibility of both consequence and probability by using a graphical output more compatible with societal tolerance

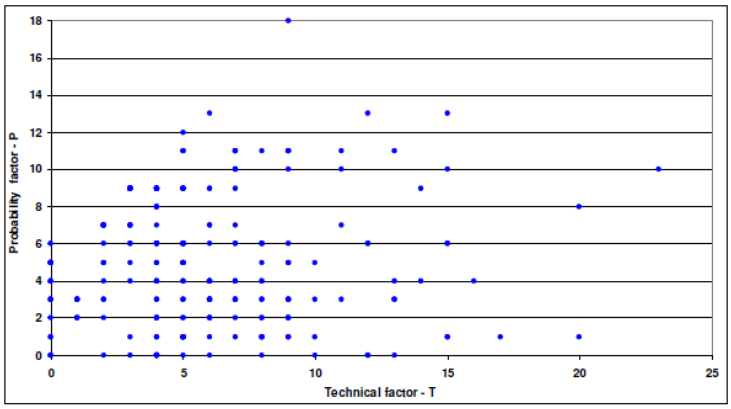
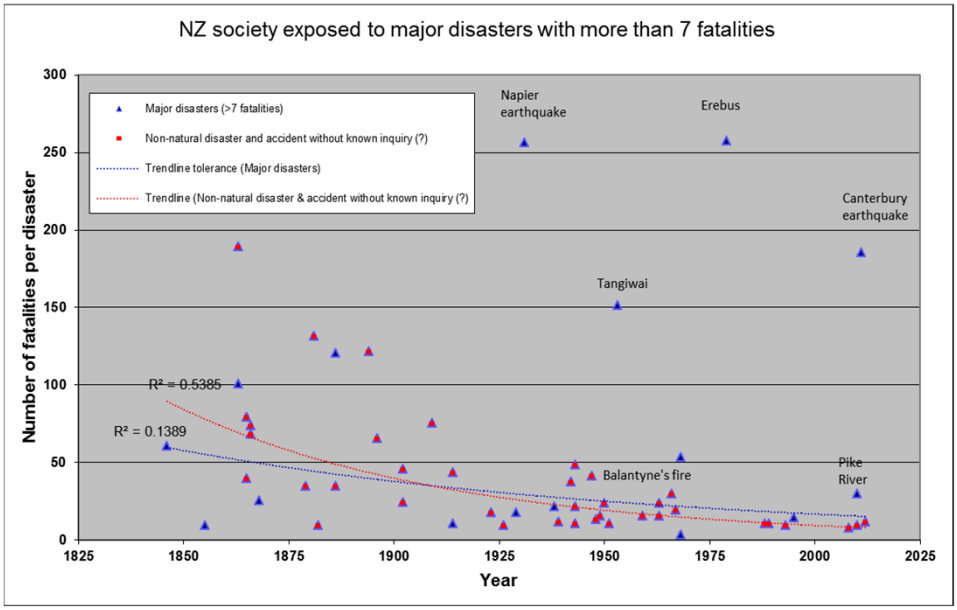


Figure 1 - Over 230 EEE with P & T factors

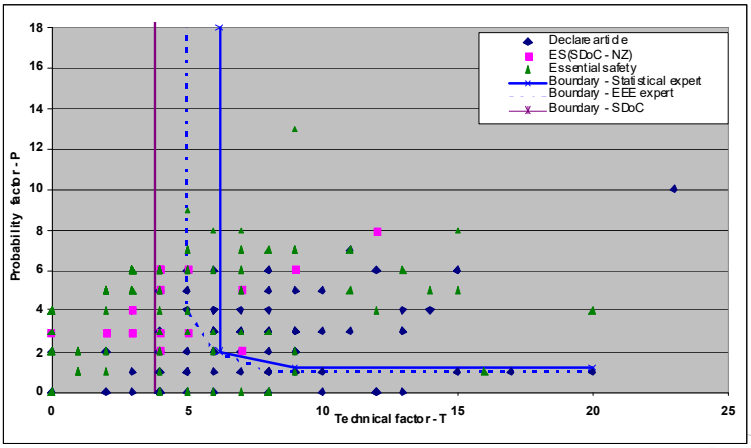


15

WORKSAFE NEW ZEALAND

Risk Category Delineation

Delineation lines are then added for the three categories using statistical analysis.



16

WORKSAFE NEW ZEALAND

Role of the engine

The engine is one part of the assessment process, it's most important role is to have a predictive look into the fog of the future

It is not the sole driver of the Regulations or post market surveillance

17

To see in the dark

18

WORKSAFE NEW ZEALAND

Probability Factors

- Product uses new technology or lacks a relevant International Standard.
- EEE that is not controlled in Australia
- EEE that is not controlled in Asia
- Product consider safe in local use only with the significant deviation to applicable international Standard.
- Product is not suitable for safe local use but can be converted to local supply conditions without significant alterations.
- Product is controlled internationally using Standards considered inadequate for local application.
- Dominant supplier's market does not use international standards or local standard.
- There are cost disincentive for compliance
- Standards recently updated
- Compliance with the applicable Standard is complex or technically difficult.

19

WORKSAFE NEW ZEALAND

Consequence Factors

- Product providing a safety functions
- Product relies on isolation between Low Voltage (LV) and exposed Extra Low Voltage (ELV) parts.
- Product likely to move during or between uses
- Product used in circumstances where he user is not able to readily disconnect with normal physical reaction to electric shock.
- Product relying on guards and barriers to prevent mechanical injury.
- Product likely to be used by unsupervised or lightly supervised children
- Product commonly used in damp locations or where the skin's resistance is by passed.
- Product's Standard is recognised as being barely adequate.
- Product subject to likely significant misuse.
- Product is high powered (heat or mechanical energy).
- Product has assessable live parts – relies on safety impedance, or current controls or cadence to achieve isolation of live parts
- Product likely to be installed by unskilled persons or relies on adjustments by unskilled persons.
- Product relies on safety cut-out for primary safety.
- Product is commonly used locally in an unattended mode but classified internationally (in the relevant international Standard) as attended.

20

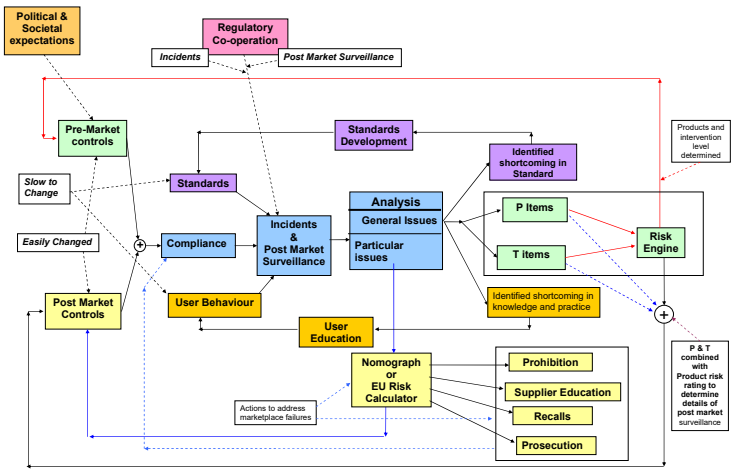
WORKSAFE NEW ZEALAND

Factors

The factors are all considered by a group of experts and a rating assigned to each factor.

Each of the factors have an equal weighting.

Role of the Risk Engine



Refinements

Since its creation the engine has had two important refinements:

After it was identified that the engine was not assessing safety function equipment, such as smoke detectors, correctly, additional factors were added to reflect efficacy compliance

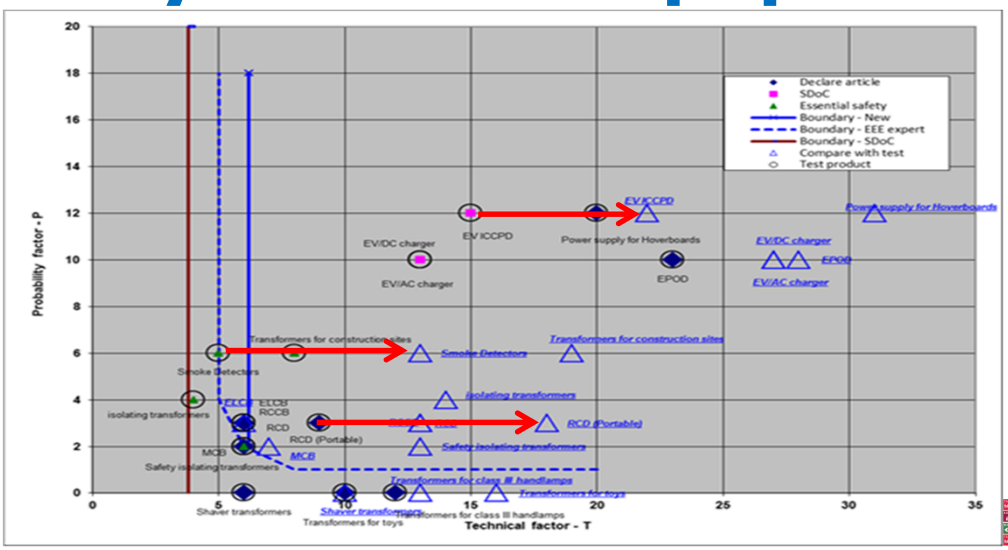
In addition the delineation lines have been reviewed.

The engine has also been recently used to assess the intervention level for Electric Vehicle charging equipment

23

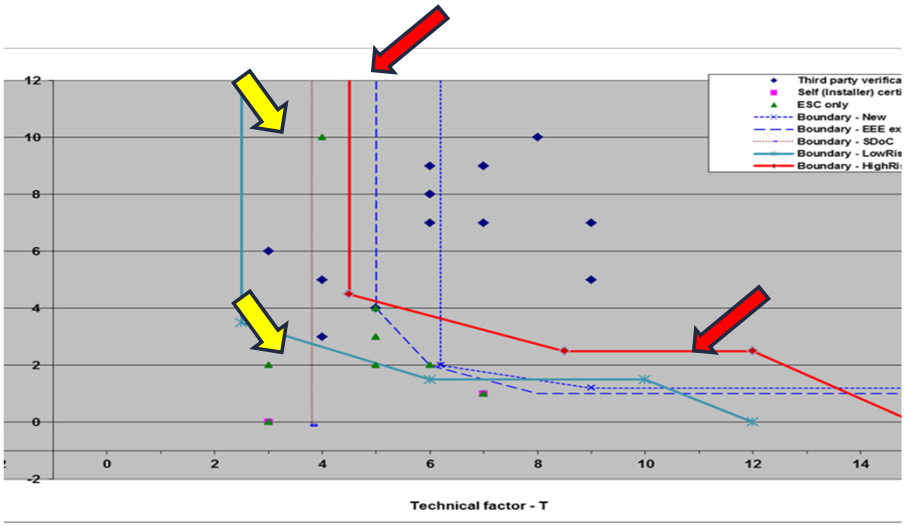
WORKSAFE NEW ZEALAND

Safety Function Equipment



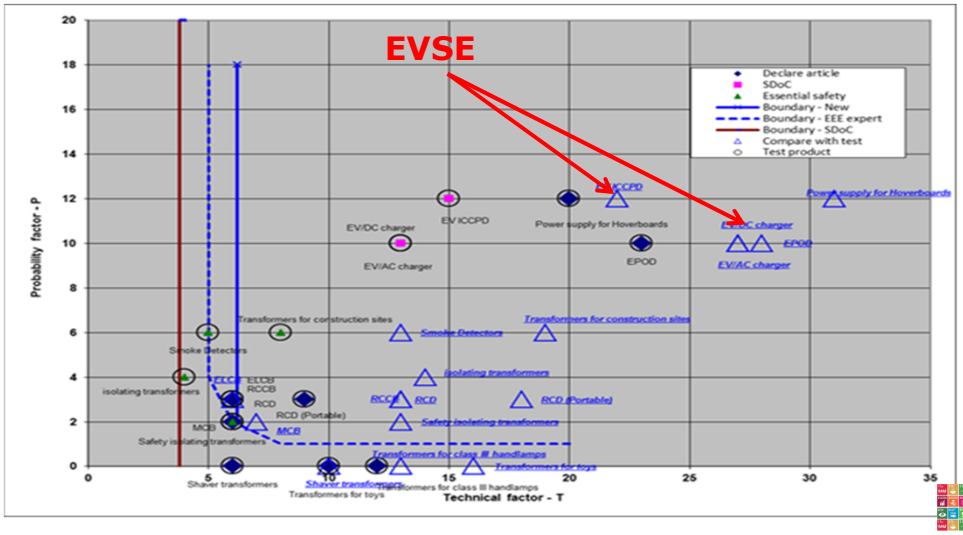
24

Delineation lines



25

EVSE Risk Assessment



26

Alignment with Australia

The Australian risk engine is almost the same as the Energy Safety (NZ) engine from which it was adopted, however, a sensitivity analysis was carried out on the engine and indicated 3 factors that were quite dominant

These factors were therefore given weighting values of 0, 0.5, or 1.0

27

ASEAN Risk Engine

28

ASEAN EEE RISK ASSESSMENT GUIDELINES

RISK Calculation for Electrical and Electronic Equipment (EEE)

$$R = C \times P \times N$$

R = The level of Risk of the product
C = The consequence of non-compliance
P = The probability of non-compliance occurring for a given product
N = The likely population of the product in the marketplace
x = multiplication sign

29

ASEAN EEE RISK ASSESSMENT GUIDELINES

$$R = C \times P \times N$$

Probability of non-compliance

✓A number of probability factors **"P"** have been identified that contribute to the probability of non-compliance. Factors that improve or reduce compliance have been identified.

✓Using the "Probability of Non-compliance Table", Annex G the product is evaluated by assigning a value to each factor.

✓A scale of 1 – 5 will be used, 1 being the lowest and 5 the highest probability of non-compliance.

✓The average of the scores of all the factors to get the value of the Probability of non-compliance.

30

ASEAN EEE RISK ASSESSMENT GUIDELINES

R = C x P x N

Final Computation

Product *(e.g.)*	**C**	**P**	**N**	**Risk factor (R)**
Product 1	4	1.1	0.5	2.20
Product 2	3	2.5	0.1	0.75
Product 3	4	3.8	1	15.20
Product 4	2	4.2	1	8.40

31

ASEAN EEE RISK ASSESSMENT GUIDELINES

R = C x P x N

Determination of applicable Conformity Assessment (CA) System

Product *(e.g.)*	**Risk Factor (R)**	**Level of Risk**	**Applicable CA System**
Product 1	2.20	Low	SDoC or other CA procedure/scheme
Product 2	0.75	Low	SDoC or other CA procedure/scheme
Product 3	15.20	High	System 5
Product 4	8.40	Medium	System 1

32

Assessing bias against females in Standardisation

Energy Safety is also a member of Working Party on Regulatory Cooperation and Standardisation Polices (WP6) UNECE-Mainstreaming Gender in Standardisation

Energy Safety has proposed that a risk engine could be developed to assess the risks of gender bias and standardisation activities.

The engine would operate by looking at the factors that lead to an increased probability or consequence of a Standard having a bias against females?

33

Factors that contribute to probability of a bias

Factor	P1	P2	P3	P4	P5
Description	The committee membership is not balanced	Females are not able to, or are not resourced to participate	No organisations are included that represent females	The consultation process does not have specific consideration of Gender Bias	There is not a verification process for the inclusion of gender issues

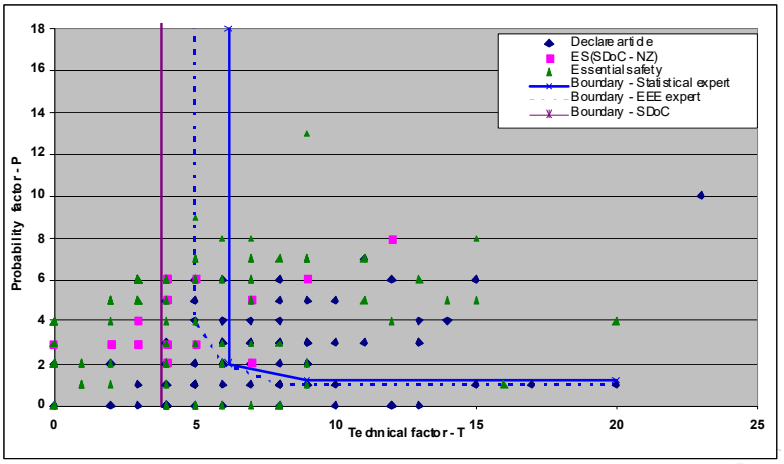
34

Factors contributing to the consequence of a bias

The standard covers a subject where men and female are physically different	The standard relates to a sector dominated by males	The bias has a significant outcome	The standard relates to a subject area recognised to be able to have a bias	The applicability of the standard to females has not been identified	The Scope of the standard is not inclusive of the impact on people	The effect of a bias is not easily understood

35

A Predictive semi-Quantitative risk assessment "engine"



36

WORKSAFE NEW ZEALAND

Getting you home healthy and safe.
That's what we're working for.

WORKSAFE NEW ZEALAND | MAHI HAUMARU AOTEAROA