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The New Zealand Electrical Products Risk Engine

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Рабочая группа по политике в области стандартизации и сотрудничества по вопросам нормативного регулирования
ЕВРОПЕЙСКАЯ ЭКОНОМИЧЕСКАЯ КОМИССИЯ

The New Zealand Electrical Products Risk Engine:

Risk Engine Design

1. New Zealand's risk assessment system for electrical product - the Risk Engine – was developed for the assessment of product for NZ's electrical and electronic equipment (EEE) safety Regulatory regime. It is broadly based on the concepts embodied in AS/NZS 4360:2004 - Risk management

2. This paper is not intended to describe in detail how risk management, or the Engine, is applied in the broad sense to the EEE safety regime, but to describe the risk assessment technique applied to assist with determining appropriate levels of pre-market regulatory intervention.

3. The Risk Engine approach allows the risk related to products placed into the market to be evaluated and treated by means of the application of a range of regulatory and non-regulatory controls in a rigorous and consistent manner.

4. The NZ regime for EEE uses three levels of pre-market intervention (See section "Premarket intervention"). Most product falls into the lowest level 'low risk' category. This category includes product that has common electrical hazard attributes but does not have sufficient higher risk attributes, or history, to place it in a category that warrants a higher level of intervention. Product in this category is controlled by setting 'essential safety' requirements that apply universally to all products.

5. The Risk Engine has therefore been developed principally to be applied to determine the levels of regulatory intervention applicable for the various items of EEE. In particular it identifies product for which inclusion in the pre-market regulated medium and high risk categories of New Zealand's EEE regulatory regime is justified.

6. While most existing risk assessment tools used internationally for EEE, derive risk values using <u>qualitative</u> assessments of risk that rely on 'expert' opinion, New Zealand's Risk Engine applies a <u>quantitative</u> assessment system based on product-specific features and identified market factors that influence compliance with the safety regime.

7. This quantitative system has been developed because it has advantages over existing qualitative systems which either rely on the analysis of incidents and post market surveillance data; or apply the opinions of very experienced experts, or combine (integrate) the opinions of a broad group of experts. A quantitative system does not have the same time lag while experience is gained in the marketplace. *A quantitative system is able to be more **systematic, objective and consistent**.*

8. Such predictive capability is especially important in an evolving market with dynamic product development.

9. Most existing risk assessment systems used for regulatory purposes apply the "in market" or "product" risk by considering the dangers created by a given appliance. This, however, depends on the adequacy of the applicable product standards and the dangers associated with the use of the product. In general, such a risk analysis is unreliable when used to determine intervention levels because it reflects the inherent dangers that the product will exhibit even when fully compliant.

10. To be effective, existing risk assessment systems are combined with accident and incident data, and this introduces a considerable time lag, especially in small markets, and may result in interventions being too late.

11. For a risk analysis to be effective, and have a predictive capability that enables it to determine levels of intervention, the analysis must focus on factors that can be addressed (countered) by the intervention.

12. The New Zealand Risk Engine applies the principle that an objective of regulatory intervention is to increase the certainty of the compliance of a regulated product with its applicable product standard, and thus improve safety outcomes both at the individual and at the market level.

13. The most basic qualitative risk analysis methods express risk by an equation such as $R=P*C$, where P is related to the likelihood of the circumstances giving rise to the risk and C is related to the consequence. The Risk Engine described in this paper quantifies risk by the formula: $R=\int(P, T)$. These factors are described in the following paragraphs.

14. Regulatory intervention offsets the likelihood (probability) of non-compliance that would occur without that regulatory intervention. The likelihood of non compliance is driven by a series of factors, most of which relate to 'market' conditions, which can be defined and assessed. This likelihood of non compliance is used as the 'Probability' factor "P" for the engine. In this model, P is the sum of a set of individual factors ($P = \sum P_i$) that, if present, contribute to the likelihood that a class of equipment will be non-compliant and thus create a hazard. *[The potential for the equipment to create a hazard].*

15. The 'Consequence' factor is derived by considering what technical features the product in question has that make it likely to create harm or damage if not compliant with its applicable product standard. These are chosen to be the recognised features above those present as a base level in the majority of product. *Control of these base level features is applied through the low risk product controls that rely on setting the essential safety parameters necessary to achieve an acceptable level of safety.* The 'Consequence' factors are also referred to as the "T" (technical safety) factors in the engine. The factor T, the technical 'consequence' factor, is the sum of a number of individual factors ($T = \sum T_i$) related to the potential for harm *[or damage].*

16. Both the P and the T factors have been validated by referral to a panel of experts. They are then applied in a quantitative manner. This creates a more repeatable and reliable assessment when compared to the qualitative 'expert' assessments.

17. The two factors are functionally combined. However, because the relative importance of P and T is not recognisably identical, nor linear, a graphical method has been employed where P and T are plotted on the two axes of a graph. This allows the contributions of both factors to be seen and considered in the assessment, a feature not present in current software systems used to establish risk ratings.

18. Delineation lines are then drawn on the graph. These lines have been separately derived, to delineate the P and T value zones where different regulatory intervention levels should be applied. These delineation lines were set for the New Zealand Risk Engine, based on a synthesis of expert opinion. Experts were asked to rate a range of items into three categories using their own judgement, and their responses were statistically combined and analysed to produce a pooled expert assessment for use as a reference for the Risk Engine.

19. Each product considered for regulation is separately assessed for its P and T values and the results plotted on the graph and the appropriate level of regulation determined.

P & T factors

20. The T factors established for the Risk Engine are listed in Schedule 1. At this time 20 factors have been identified and applied. These factors reflect the types of technical issues that significantly affect the safety of a particular appliance when it is not complaint with its applicable Standard.

21. The P factors for the Risk Engine are listed in schedule 2. In the current assessments, 10 factors are applied. However a revised grouped set of factors has been developed and this is being assessed for future implementation (see Schedule 3). These factors have been derived by consideration of what market features influence compliance.

22. Both the T and P factors were compared with the factors that the panel of experts advised had influenced their own assessments of individual product risks.

23. The engine derives the overall P and T values that are applied by simply summing the number of individual P or T factors exhibited by each product under consideration. Each of the individual factors is given an equal contribution (value) in the assessment.

Benchmarking and validation

24. The development of the Engine has involved an ongoing process of testing and validation. Two processes have been used for the validation engine: The use of a panel of “experts” to provide peer advice on the factors and to independently assess the risk of the majority of the products being assessed using the Engine. And, a comparison of the output of the Engine against the list of products considered to justify increased intervention based on historic data, including the factors known to have influenced past decisions to implement increased interventions.

25. When the development of the Risk Engine began, an analysis of the existing system was performed using the historic method to provide an auxiliary benchmark for the engine.

26. During development of the Engine, a system of weighting the individual factors was trialled, however the 'accuracy' of the weighting was difficult to determine, and the effect of this approach was to make the system less accurate when applied against expert and historical benchmarks.

The system in operation

27. The Engine presently contains assessments of 234 products, mostly ‘domestic and similar appliances’ and fittings.

28. The graphical output of the Engine’s assessment of the 234 products is shown in Figure 1. The spread of the products can be seen, with those having the highest rating in the top right hand side of the graph.

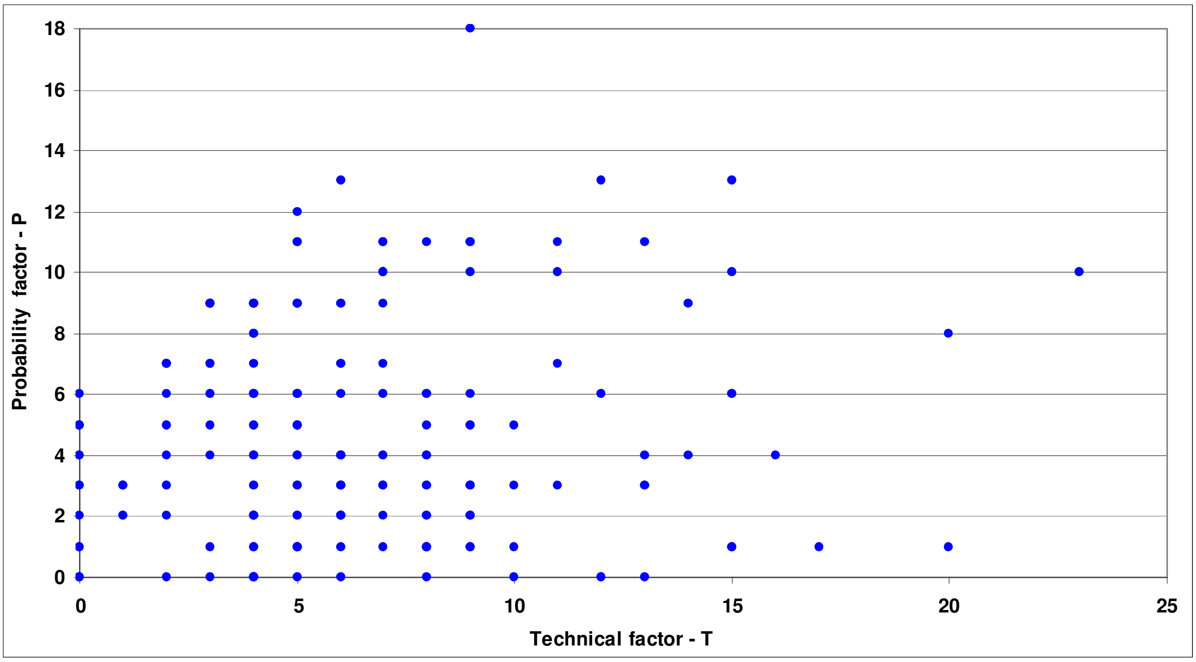

Figure 1 - Over 230 EEE with P & T factors

29. Figure 2, shows the two delineation lines established for the Engine to delineate the high and medium product ratings. The statistically derived boundary, based on the ratings provided by the experts, is shown as a dashed 'curve'. *The analysis of the expert input did not create a reliable delineation into three zones but did create a reliable delineation into two zones.*

30. There are certain products for which the certainty of compliance if regulated in a light handed manner might not meet society's expectations, yet the cost of compliance at the higher level of intervention may not be justifiable. The use of an intermediate category provides a method of increasing compliance certainty with a more realistic compliance cost.

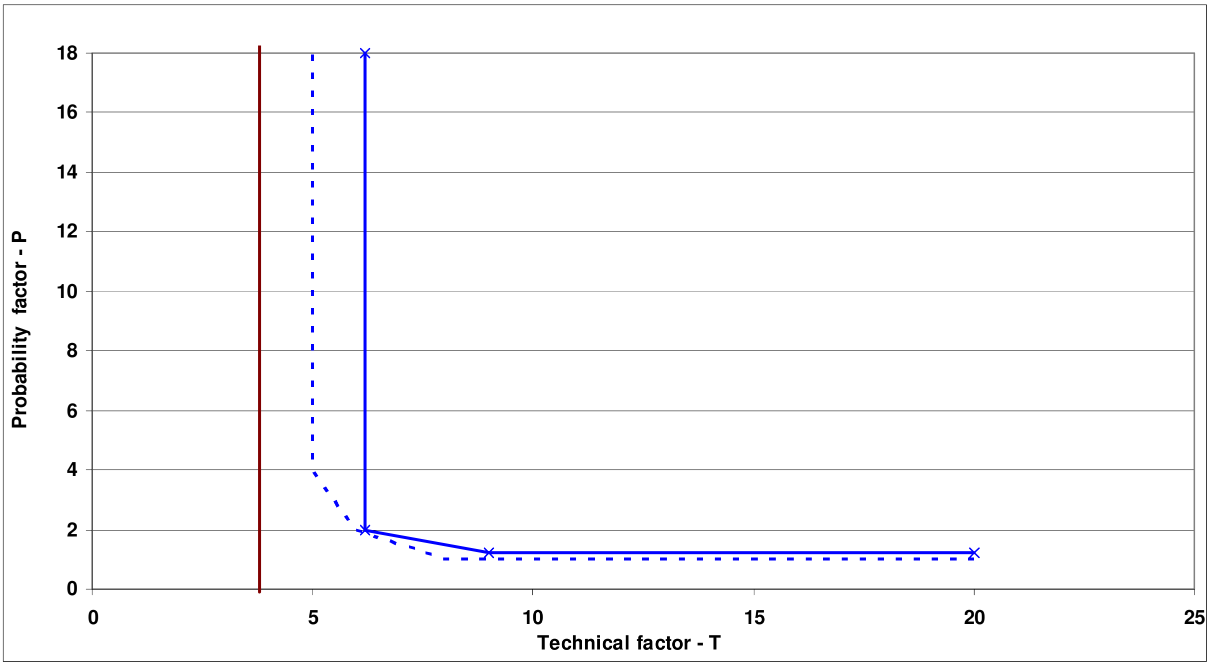

Figure 2 - Risk Engine delineation lines

31. The spread of equipment on NZ’s present Declared Article (high risk) list is shown in Figure 3. The present Declared Article list was established prior to the development of the Engine using historic incident and post market surveillance compliance results, and was relatively recently ***(2002)*** refined using New Zealand experts’ opinions. There is a good correlation with the rating of the Engine.

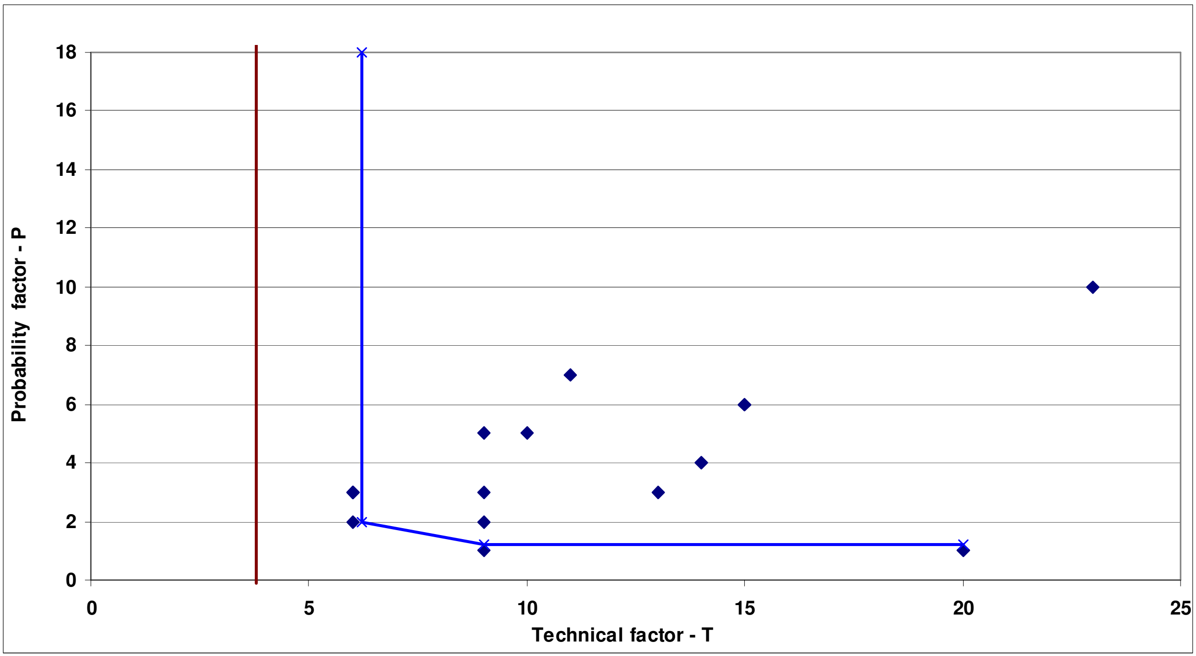

Figure 3 – Current NZ Declared Articles on T-P graph

32. Figure 4 , shows the spread of NZ's present 'medium risk' Supplier Declaration (SDoC) items. These items are mostly based on the Australian Declared Article list, and as a result are a little less applicable in New Zealand. They are also somewhat more historically based, having not been subject to the same recent review as the New Zealand declared article list.

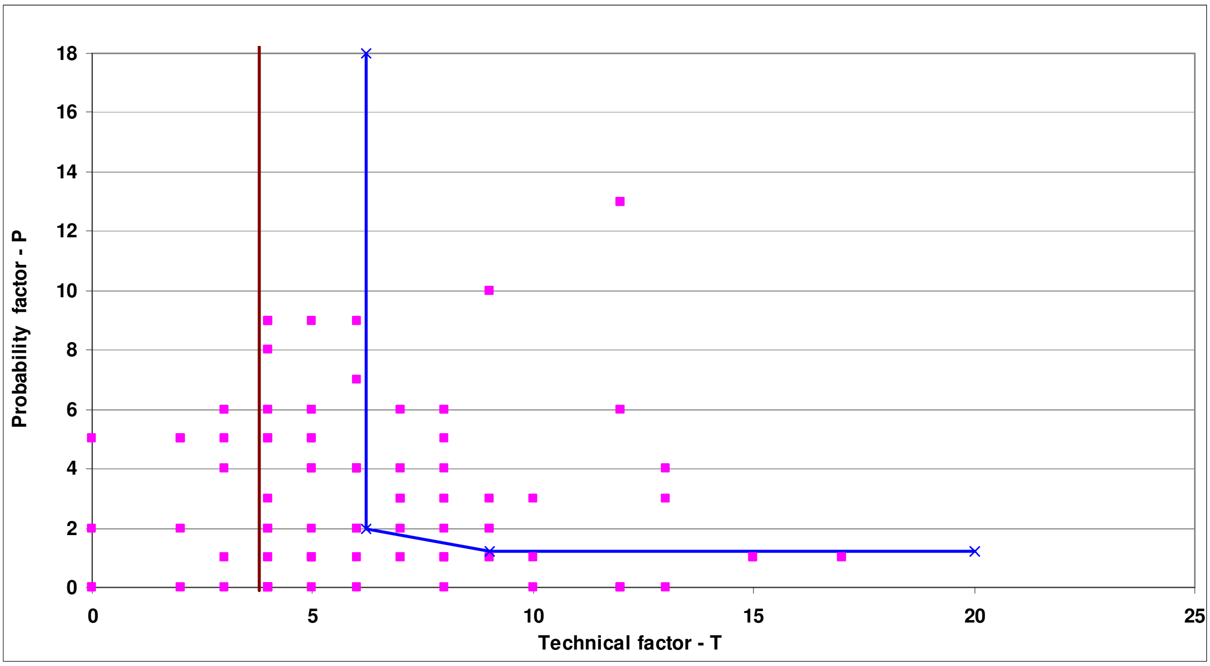

Figure 4 – SDoC items

33. The spread of the present ‘low risk’ items is shown in Figure 5.

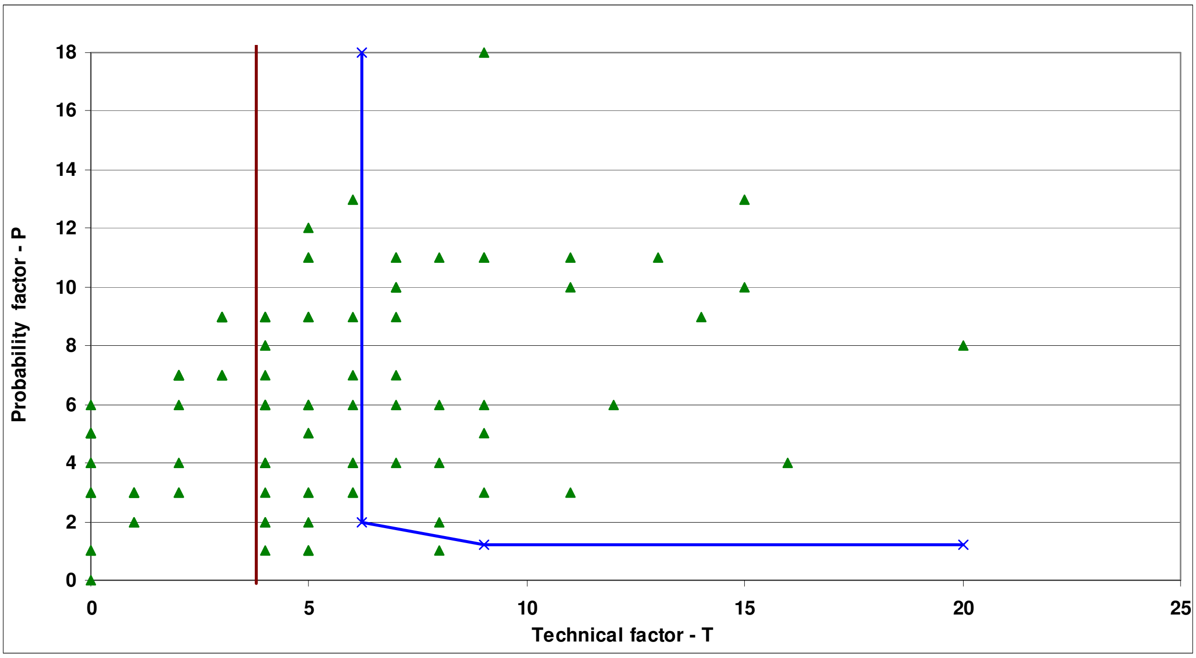

Figure 5 - Essential safety

34. These graphs indicate that a number of products justify adjustment to their allocated listings in NZ. It is proposed therefore to adjust the lists where the ratings are significantly different from the controls being applied at present. These adjustments however will be carried out in consideration of the TTMRA and the present review of the Australian Regulatory Regime being under taken by ERAC.

Australian Regime Review

35. Australia is presently in the final stages of reviewing the State and Territory regulatory controls applied to Electrical and Electronic Equipment (Products).

36. This review proposes to replace the present Australian two level system with a three level system similar to the New Zealand system, and to establish the controlled items using an assessment system closely based on the New Zealand Engine. During the time that this system is established in Australia, New Zealand will move to align the New Zealand system as far as possible, fulfilling the two Governments’ vision of a single economic market.

37. In this context, it is therefore sensible in the short-term, to refine the New Zealand regime only where significant differences exist between the assessments and the existing controls, which are already closely aligned with Australia, as such changes would be reasonably likely to occur when Australia implements it’s own review.

TTMRA implications

38. The Trans-Tasman Mutual Recognition Agreement (TTMRA) places an obligation on New Zealand to maintain adequate controls over products to "protect" the Australian marketplace. As a result any changes should also take this expectation into account. Consequently, no products will be removed from the medium risk category that are declared articles in Australia.

Pre-market versus post-market controls

39. Compliance of products within a marketplace can be influenced (Regulated) through both pre-market and post-market systems of intervention. Both systems have particular advantages and disadvantages.

40. The assessments of the engine can be used to determine where to apply either or both systems. For example; a high risk product might be controlled by a mixture of premarket intervention at medium level and intensified post market surveillance, or alternatively, a higher level of premarket intervention and a lighter level of post market surveillance.

Pre-market intervention

41. As already discussed, New Zealand operates a three level system of electrical equipment regulation. The lower level simply applies a requirement for the equipment to be safe and parallels the consumer protection expectation that products are "fit for purpose". A range of recognised Standards are cited for determining acceptable levels of safety.

42. A Standard describing the relevant safety parameters (not unlike the EU LVD) is recognised as an alternative where new technologies or unusual products are beings assessed. This system implements the WTO expectation for performance based regulation.

43. High risk products are required to be type tested and certified by a third party or given an approval by a recognised Regulatory Agency – usually the New Zealand regulator or an Australian Regulator. This generally requires the product to have been tested by an accredited testing laboratory. In international terms this represents an ISO Guide 67 Type 1 certification system.

44. Medium risk products are required to be covered by a declaration of safety, SDoC, made by a New Zealand based supplier (the importer or manufacturer). The declaration is required to be made in accordance with ISO 17050 and is required to be accompanied by a test report. The test report however is not required to have been produced by an accredited CAB. The system also recognises; product certification under the New Zealand – China EEEMRA, product certification under New Zealand's other MRAs, approval by an Australian regulator, or, certification by a JAS-ANZ accredited certification body, as being equivalent to a test report.

45. The medium risk category therefore is considered to have an intervention level at about the mid point of the low and high risk requirements.

Implementation

46. It is proposed to apply the engine to adjust the list of products controlled as Medium and High Risk products under the new Regulatory Regime.

47. In addition to the implications of the TTMRA and the Australian Review, it is also proposed that no product will be implemented in New Zealand as a high risk item if that item is not presently a declared article in Australia, as this would create a significant compliance cost. In cases where products are assessed as high risk, but are not DAs in Australia, New Zealand will implement the products as medium risk, and increase the level of surveillance to compensate as necessary.

48. As the lists are adjusted, a transition period will be allowed to ensure that the industry is able to adjust without significant cost or disruption of trade.

Schedule 1

Technical (Consequence) factors

- Product that provides an electrical safety function.
- Product that relies on isolation between LV and exposed ELV parts.
- Product that is likely to be moved during or between uses.
- Product that is used in circumstances where the user is not able to readily disconnect themselves with normal physical reaction to electric shock or burns.
- Product that relies on guards and barriers to prevent mechanical injury.
- Product is likely to be used by unsupervised children.
- Product commonly used in damp locations or where the skins resistance is bypassed.
- Product's standard is recognized as being barely adequate.
- Product subject to likely significant misuse.
- Product is high powered (heat or mechanical energy).
- Product has assessable live parts and relies on safety impedances, current control or cadence for safety.
- Electrical installation related product, likely to be installed by unskilled persons.
- Product relies on safety cut-off or interlock for primary safety.
- Product is commonly used locally in an unattended mode but classified internationally as attended.
- Product that contains high stored energy.
- Product that has an ionising radiation hazard.
- Product that has hot accessible non-working surfaces.
- Product that has a toxic output.
- Product where a critical failure is not likely to be visible or recognised.
- Product that is generally electrically interconnected with other products.

Schedule 2

Probability factors

- Product generally incorporates new Technology.
- Product is not regulated in Australia.
- Product not generally regulated in Asia.
- Product subject to a deviation from the relevant international Standard.
- Product can be easily converted from a 110 volt product.
- The applicable international Standard is considered to be inadequate.
- The dominant supplier's marketplace applies a standard considered to be inadequate for New Zealand.
- There is a significant compliance cost disincentive.
- There has been a recent update in the relevant standard.
- Compliance with the applicable Standard is difficult to achieve.

Schedule 3

Revised Probability factors

- **Testing is:**
    - expensive
    - difficult
    - not readily available in dominant supplier's markets
    - not readily available internationally.
- **Adequate Standard does not exist:**
    - in the local market
    - in the dominant supplier's markets
    - internationally.
- **Regulatory Control** – Product is not controlled in:
    - regional market
    - dominant supplier's markets
    - global markets.
- **Deviations** – Relevant standard deviates from:
    - regional Standard
    - dominant supplier's market standard
    - international Standard
    - another significant market's standard.
- **Compliance disincentives** from:
    - cost
    - complexity
    - inappropriate conversion.
- **Changes to product designs** have resulted from:
    - amendments to applicable standards
    - other regulatory requirements
    - new technology applications.