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DEFINING THE PRODUCT-BASED NON-CONFORMANCE CLASSIFICATION

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ABSTRACT

This paper focuses on the identification of non-conformances to facilitate improved product validation and aids the pre-production team in product assessment. The manifestation of mistakes which results in non-conformances and their relationship with the characteristics of the product under validation is explained. A new non-conformance classification has been defined based on the manifestation of mistakes and product characteristics. The classification has been evaluated by experts on consumer electronic products from multinational manufacturing companies through closed and open ended questionnaires. The respondents described the classification to be feasible and applicable in pre-production. The proposed classification contributes to the understanding of mistakes and product quality deficiencies which can be minimised by addressing non-conformances during product validation.

Keywords: *Non-conformance, mistakes proofing, product design and development, pre-production, quality, validation*

INTRODUCTION

In the Product Development Process (PDP), products which are found to be outside specification are said to be non-conforming and can be a major cost to manufacturing industry. Non-conformances contribute to unreliable product quality, which shows up, for example, as functional failure (Almgren, 2000) and poor appearance. Whilst most non-conformances are manifested and identified at the later stages of product development, they often escape into production and into the hands of users (Booker, 2003). Hence, the later non-conformances identified, especially late in development, the higher the cost incurred to rectify a product (Milne, 1994, cited in de Castro and Fernandes, 2004). The reasons for pre-production are validation and verification of products prior to production to ensure product conformance with specification and quality requirements (Jamaludin and Young, 2005). Companies describe non-conformances in a distinctive manner, for example by colour coding, numerical, or the simple no/no-go. The decision on how to assess non-conformances depends on the perception and experience of the senior staff in the company. This results in inconsistency in dealing with non-conformances when different people and circumstances exist.

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Therefore, without a consistent understanding of non-conformances, it is difficult to address non-conformances comprehensively and, hence, to conduct an effective product validation process.

Product non-conformances are known to arise from three sources: complexity, variation, and mistakes (Hinckley, 2001). Excessive complexity and uncontrolled variation result in increasingly difficult to understand about products and production processes, and whilst mistakes are seen as the major source of non-conformances (Hinckley, 1997; 2001; 2003), the consequences are significant. A study has found that of 23,000 production defects, 82% originated from mistakes (Hinckley and Barkan, 1995; Hinckley, 1997), and most of the mistakes are human-generated (Nikkan Kogyo Shimbun, 1988).

There has been a lack of empirical studies on the understanding of non-conformances, and the methodological principles of how to improve product validation in pre-production (Almgren, 2000; Nagasaka, 2000; Liu and Cheraghi, 2006). Most research describes non-conformances either from a broad or narrow aspect. The broad aspect describes non-conformances in the context of the overall product development process with cost as the main focus of discussion (Crosby, 1979; Deming, 1986; Juran and Godfrey, 1999), while the narrow aspect presents mathematical and statistical analysis in problem solving on a specific non-conformance issue. The lack of academic works and industry inadequacy in addressing product non-conformance has been reflected in *failure in understanding of non-conformances extensively*. Hence, there is a need for a holistic understanding of non-conformances, by understanding the manifestation of non-conformances and the product under validation.

The focus of the research is on product non-conformance in pre-production, with the aim of improving methods for delivering high quality products. The formulation and development of the research ideas had evolved from the understanding of product non-conformance and validation process in pre-production. The proposed method have been evaluated by experts from six multinational manufacturing companies who have authority in the product development process and involved in product validation. The study reported in this paper contributes to the domain of product quality within the Product Development Process.

PRODUCT VALIDATION PROCESS

A typical product validation process is illustrated using the IDEF0 activity modelling method (Bal, 1998; Cheung and Bal, 1998; Dorador and Young, 2000), as depicted in Figure 1 (non-conformances are identified and classified based on the new classification, the Product-based Non-conformance Classification.). The validation process consists of five elements; Input, Output, Controls, Mechanism and Process.

The *input* represents the product to be validated on either a new or improved product. The *output* is the product which completes validation in two conditions: (i) the product is in conformance and qualifies for production, and (ii) the product is non-conforming and requires further scrutiny. The *controls* represent the validation consideration i.e. specification and quality requirements. The *mechanism* for checking product conformance and non-conformances is by means of inspection. The *process* is the conduct of the validation and relates to all four elements described earlier. The model is adopted as it represents the validation process, the associated elements and their relationship in an easy to understand model which non-experts can view and understand (Dorador and Young, 2000).

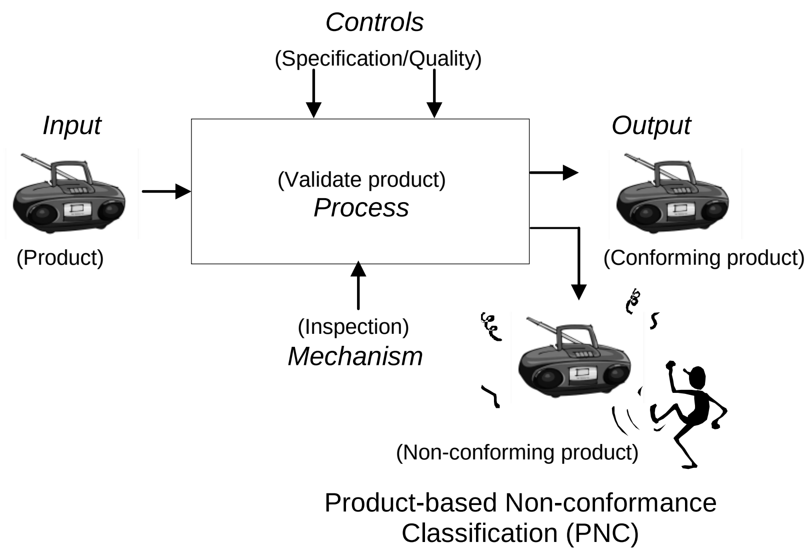

Figure 1
Typical product validation model.

The research has identified three interrelated characteristics of product under validation i.e. Information, Process and Parts/Components, as shown in Figure 2. The arrows pointing towards the product represent the product's characteristics, while the dotted arrows are the relationship between these characteristics. For example, when inspecting one aspect, it is necessary to counter-inspect with the other aspects. As such products are validated for integrity among the characteristics, as dictated by the specification and quality requirements.

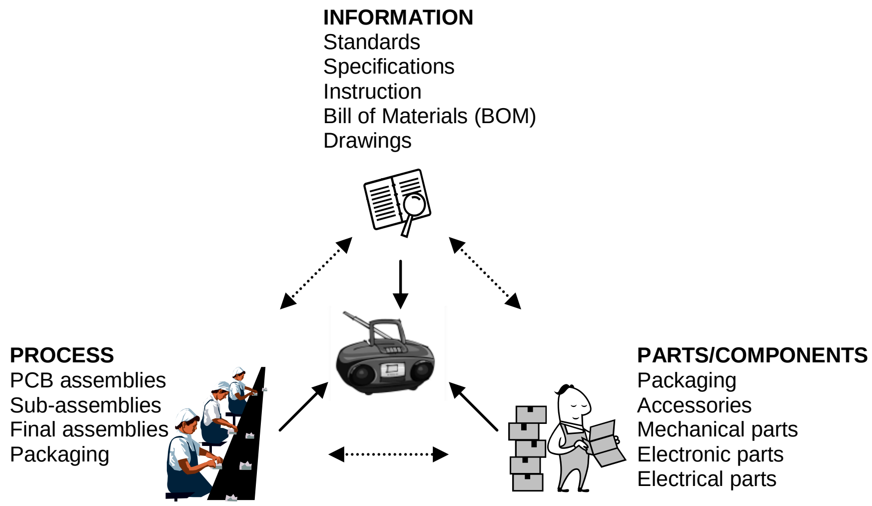

Figure 2
Three interrelated product characteristics in pre-production.

The pre-production of typical consumer electronic product is accompanied with a complete set of control documents or *information*. These are technical documentation pertaining to the product and its assembly process. The documents are specification, drawings, Bill-of-Materials (BOM), standard procedures and instruction, and Engineering Change Orders (ECO). In the trial-run, the whole *assembly process* is looked into according to assembly information such as the work instruction and assembly drawings. The assembly lines typically consist of printed circuit board assembly lines, sub and final assembly lines, and packaging lines. Then, all *parts and components* listed in the BOM are delivered to the assembly lines and assembled according to the assembly drawings and work instruction. The parts and components are grouped into packaging materials, accessories, and functional parts (mechanical, electronic and electrical).

VALIDATION ASPECTS DURING PRE-PRODUCTION

Product validation focuses on the items within this three product characteristics, i.e. information, process and parts/components, thus the identification of non-conformances should be directed on these items. The details of the validation considerations are listed in Tables 1, 2 and 3. Any deviation from specification and quality requirement identified in the product's characteristics during validation represents the manifestation of non-conformances. Therefore, non-conformances are classified based on their manifestation on these three characteristics.

Table 1

List of validation considerations related to Information.

Particulars	Information Description
Drawings	▪ Complete set of the most recently approved assembly, detail and working drawings. ▪ Information on drawings identification, for example drawing number, title, page number, dimensions, notes, amendments, symbols, conventions, etc.
Bill-of-materials	▪ Most recent approved documents with complete list of mechanical and electronic parts and components, and sub-assemblies.
Packaging	▪ Printed identifiable product information, for example labels, graphics, colour, languages, instructions, messages, numbers, characters on the carton boxes, plastic/paper wrappers and polystyrene-foams, bar-coded product information, etc. ▪ Safety information on carton boxes, plastic wrappers, and polystyrene foams, for example weight, size, handling orientation, stacking guides, safety messages and instructions, etc. ▪ Complete set of accessories printed materials. ▪ Instructions, manuals, booklets, warranty card, reply cards, for example for all accessories, with part name and part numbers, labelled, correct languages on printed materials.
Product safety	▪ Assembled, sub-assembled parts, mechanical and electronic components are clearly labelled or imprinted with safety messages, warnings and instructions in compliance with safety standards and specifications.
External and internal features	▪ Brand logo, model identification (name of model and unique number on stickers or imprinted); labelling for functions and features (for example power on-off, volume, left/right, etc.). ▪ Dismantling instructions, messages, warnings and instructions all around and inside the product.
Parts and components	▪ To tally with detail and assembly drawings, for example dimensions, type of material, colour, etc.

Testing and measurement	▪ Testing and measuring the electronic and electrical values as per specification and safety requirements. ▪ Quality and reliability testing and measurement, including information for packaging specification.

Table 2

List of validation considerations related to Process.

Aspects	Process Description
PCB assemblies	▪ Both automated and manual insertions, for example new and additional components, components to be removed or replaced.
Sub-assemblies	▪ Sub-assembled parts, for example product modules, CD/cassette drivers, PCBs. ▪ Fitting of loose parts, for example bolts/nuts, plastic fasteners, joints, brackets, housings, washers, wiring, lids, bases, etc.
Final assemblies	▪ Fitting all sub-assembled parts and modules according to procedures, with special care.
Packaging	▪ Packing of items with packaging materials using appropriate methods, sequence and orientation of packaging. ▪ Instruments, tools, equipment, and handling. Attention will focus on the type of tools needed to assemble the product. Where necessary, jigs, gauges and fixtures will have to be supplied. Special requirements for tools, equipment, handling methods or even testing instruments are avoided as much as possible.

Table 3

List of validation considerations related to Parts/Components.

Particulars	Parts/Components Description
Packaging configuration	▪ Carton boxes. ▪ Plastic wrappings for product and accessories. ▪ Polystyrene foam (protecting product). ▪ Packing seals and cushioning (bubble packs).
Accessories	▪ Complete set of printed materials, for example warranty cards, reply cards, manuals, instructions booklets. ▪ Complete set of accompanying items, for example remote controls, cables, loud-speakers, batteries, antenna, and other related items.
Product	▪ Physical and appearance. ▪ Casings (front panel, rear panel, base, lids, and battery lids), colour, materials, stickers, etc. ▪ Moving mechanism, for example buttons, CD trays, sliders, cassette decks, antenna, handles, knobs, and other parts. ▪ Cables and fittings, for example power supply, external antenna, speakers, microphone and headphones. ▪ Mechanical and electronic assemblies. ▪ Fittings, housings, brackets, fasteners, joints. ▪ PCBs (main board, tuner board, AV boards), LEDs, miniature components, wire harnesses, displays, motors, cables and wiring connections, etc.
Functionality	▪ Conditions and features as per requirement and working together with accessories.
Safety	▪ Visual, audible and tactile check on mechanical parts, for example sharp and pointed edges, loose assemblies, breakages, foreign materials, etc. ▪ Visual and audible inspection, and testing on wiring and cables insulations, labels, colour codes, warning signs, jacks and insertion, LEDs, etc.

DEFINING PRODUCT NON-CONFORMANCES

The research has identified those product non-conformances in pre-production as having two distinctive aspects,

- *Non-conforming items are the results of mistakes*. These mistakes have been identified in the product's characteristics, as shown in Figure 3, and

- The Outcome-based Classification by Hinckley (2001) describes mistakes identified in production into five groups: defective material, information errors, misses, selection errors, and omission/commission errors. In pre-production, similar mistakes which result in non-conformances are *manifested in the product's characteristics*.

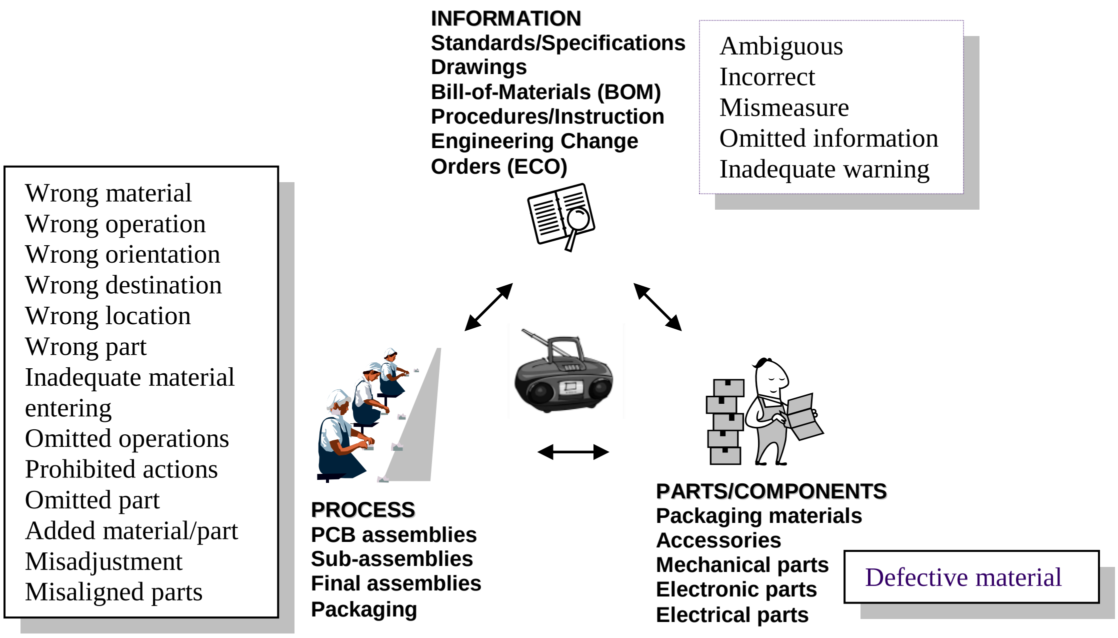

Figure 3
Relationship between product characteristic and type of mistakes.

Thus, a generic classification of non-conformances which relates to mistakes and product characteristics is introduced. The classification is called the *Product-based Non-conformances Classification* or *PNC* (Jamaludin, 2008) As shown in Table 4, the classification consists of three types of non-conformances corresponding to the product's mistakes and characteristics:

- Information Non-conformances,
- Process Non-conformances, and
- Parts/Components Non-conformances.

The potential of the PNC is that the approach should be able to aid in identifying non-conformances with the following important features:

- Each product characteristics has a known type of mistakes, likewise any mistakes can be tangibly identified with the corresponding characteristics.
- Mistakes in one product characteristic correlate with other characteristics, as shown in Table 5. This shows that one mistake is related to other mistakes; hence one class of non-conformance is correlated with other classes of non-conformance. For example, wrong operation (process non-conformance) is strongly correlated with defective material (parts/components non-conformance), incorrect information (information non-conformance), and omitted operation. This ensures that potential non-conformances are not ignored or overlooked. The table depicts holistically how mistakes, product characteristics and non-conformances are correlated. Therefore it is important to identify other potential non-conformances within the three product characteristics.

Table 4

Classes and location of non-conformances, and potential mistakes.

Class of non-conformance	Locality of non-conformances	Type of mistakes	Description of mistakes
Information	Technical specifications Work Instructions Bill-of-Materials Drawings Checklist Engineering-change-order	Ambiguous Information	Information can be interpreted many ways, some interpretations may be incorrect.
		Incorrect Information	Information provided is incorrect.
		Misread, Mis-Measure, Misinterpret	Gauge-reading errors, errors in measuring, or errors in understanding correct information.
Process	PCB assemblies Sub-assemblies Final assemblies Packaging	Omitted Operations	Failure to perform the required operation.
		Wrong Part	Part selected, but wrong part.
		Wrong Orientation	Part inserted in correct location, but the part has wrong orientation.
		Wrong Operation	Operation executed, but wrong operation.
		Wrong Location	Part insertion or process execution in incorrect location that is not the result of incorrectly orienting parts.
		Wrong Destination	After completing operation, product sent to wrong address or destination.
Parts/ Components	Packaging Materials Accessories Mechanical Parts Electronic Parts Electrical Parts	Defective Materials	Material entering process is defective or inadequate for the intended function, process, or purpose.

Subsequently, identifying non-conformances as the result of mistakes on the individual items of the product’s characteristics is much simpler. Once non-conformances are identified, it is easier rectify and to learn from mistakes (Gillingham et al., 1997).

CASES SUPPORTING THE PRODUCT-BASED NON-CONFORMANCE CLASSIFICATION

The following paragraphs exhibit typical non-conformances, as a result of mistakes, manifested on product under validation in a multinational manufacturing company which designs and produces consumer audio and video products. The exhibition represent evidence of non-conformances classified according to the PNC.

Evidence of Information Non-conformance - *Information essential for the correct execution of a process or operation is not available or has never been prepared*. Part names for assembling a component were not shown in the assembly drawings but only part number, as shown in Exhibit 4. As operators are used to identifying parts by names, parts and components were mixed or assembled with the wrong part during trial-run assembly.

Table 5

Classes of non-conformance and their related mistakes.

⊙ Strong Connection
O Connection
Blank Weak/No Connection

		P/C	INFORMATION					PROCESS													
		Defective Material	Ambiguous	Incorrect	Mismeasure, interpret	Omitted Information	Inadequate Warning	Misalign	Misadjust	Mistimed or Rushed	Added Parts	Prohibited Act	Omitted Operation	Omitted Parts	Wrong Material	Wrong Destination	Wrong Location	Wrong Operation	Wrong Parts	Wrong Orientation
P/C	Defective Material							O	⊙	⊙		O	⊙	⊙				⊙	⊙	⊙
INFORMATION	Ambiguous				⊙			⊙	⊙				O				O	⊙	⊙	O
	Incorrect				⊙				⊙	⊙		⊙			O	⊙		⊙		
	Mismeasure, interpret	O	⊙	O				⊙	⊙	⊙					⊙		O			O
	Omitted Information							O	O			⊙	O	O	⊙		O	O	O	
	Inadequate Warning							⊙	⊙	⊙										
PROCESS	Misalign	O	⊙		⊙	O	⊙		⊙	⊙			O	O			⊙			⊙
	Misadjust	⊙	⊙	⊙	⊙	O	⊙	⊙		⊙		O					O			O
	Mistimed or Rushed	⊙		⊙	⊙		⊙	⊙	⊙			O	⊙	⊙		O	O	O	O	O
	Added Parts											⊙		O					O	
	Commit Prohibited	O		⊙		⊙			O	O	⊙				O					
	Omitted Operation	⊙	O			O		O		⊙				⊙	⊙			⊙		
	Omitted Parts	⊙				O		O		⊙	O		⊙				O	O	O	
	Concept or Material			O	⊙	⊙						O	⊙					⊙	⊙	
	Wrong Destination			⊙						O							⊙		⊙	
	Wrong Location		O		O	O		⊙	O	O				O		⊙		O	O	⊙
	Wrong Operation	⊙	⊙	⊙		O				O			⊙	O	⊙		O		⊙	⊙
	Wrong Parts	⊙	⊙			O				O	O			O	O	O	O	O		O
	Wrong Orientation	⊙	O		O	O		⊙	O	O							⊙	⊙	O	

Source: Adapted from Hinckley (2001).

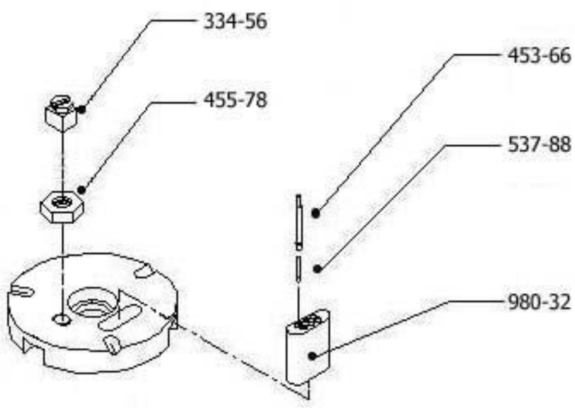

Figure 4
Omitted part name in assembly drawing

Evidence of Process Non-conformnce - *A missing part resulting from failure to comply with correct product requirement.* Often recurring non-conformances are of this nature due to the similarity of many product versions. For example, a label on the rear panel of a product was found missing during inspection, as shown in Exhibit 5. Most products use the same panel but with a different label requirement.

Figure 5
Missing label.

Evidence of Parts/Components Non-conformance - *Non-conforming parts/components are manifested when material entering a process is defective, or inadequate for the intended function, process, or purpose.* This section describes in detail the third classification of non-conformances and its connection with other classes. As shown in Exhibit 6, the two cassette lids did not open simultaneously when both eject buttons were pressed.

Figure 6
Two cassette lids open at different pace

One of the lids was suspected to be out of dimension because the lid touched the opening frame, leaving no gap. Other variables such as foreign material, gear, spring, cassette player lids, lid frame, inspection check list, and assembly methods are elements where non-conformances could occur, as shown in Exhibit 7.

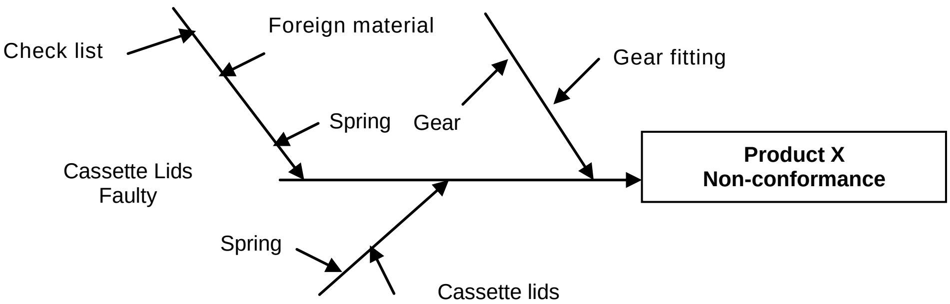

Figure 7
Elements contributing to non-conformances

There are also mistakes, such as mis-adjustment, defective material, omitted information, wrong parts, and wrong operation, which cause non-conformances. How are these two aspects linked? A cause and effect diagram in Exhibit 8 presents the connection between the elements and mistakes which contribute to non-conformances. For example, the gear was misadjusted when tightening screws with tight torque or not fitting the gear according to the pre-determined sequence (wrong operation) are the most likely causes of the faulty lid. Mis-adjustment and wrong operation in fitting the gear have high probability or strong connection for causing the faulty lid. The connection between the two aspects is presented in the connection matrix, as shown in Table 6.

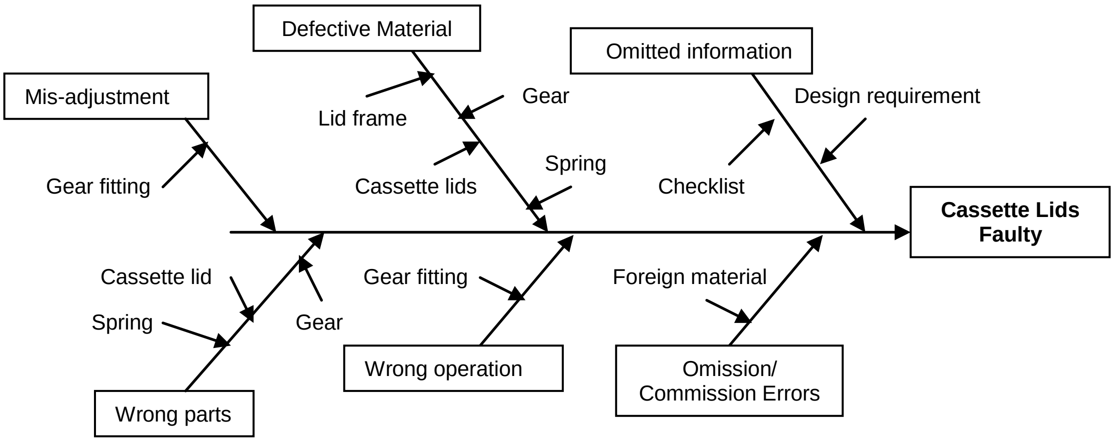

Figure 8
Elements and mistakes causing faulty cassette lid.

In summary, any deviation from specification and loss of quality identified in the product characteristics during validation represents the manifestation of non-conformances. For this reason, non-conformances can be classed based on the product characteristics.

Table 6
Connection between elements and mistakes.

⊙ Strong Connection
○ Connection

Elements		Mistakes					
		Defective material	Omitted Information	Misadjust	Prohibited Act	Wrong Operation	Wrong Parts
Cassette Lids Faulty	Gear fitting			⊙		⊙	
	Foreign material				○		
	Gear	⊙					○
	Spring	⊙					○
	Cassette lids	⊙					○
	Lid frame	○					
	Check list		⊙				
	Requirement		⊙				

EVALUATION RESULTS

The PNC has been evaluated through interviews and questionnaires with experts who are vastly experienced in wide range of consumer electronic product, having authority and involved in designing, in pre-production and production activities. The validity of the concept of the PNC is viewed from the practical and actual design and manufacturing environment.

Experts, or evaluators, from six manufacturing companies (companies name are remained anonymous) were invited to assess the PNC. The profile of evaluators, by designation, length of service, and their company’s range of product are shown in

Table 7. Evaluators were identified as A, B, C, D, E and F. A semi structured questionnaires was used to assess:

- the product characteristics,
- mistakes as the source of non-conformance, and
- the PNC.

Table 7
Profile of evaluators and companies.

Company	Evaluator Designation	Years in company	Product
A	Senior Engineer (NPI Division)	6	Hard disk drives for computers, mobile devices and enterprise storage.
B	Assistant Manager (R&D Department)	11	CRT TV, LCD TV, projector and computer monitors
C	Senior Manager (R&D Division)	13	CRT & electron devices
D	Senior Engineer (R&D Centre)	7.5	Hi-fi, radio cassette recorders & home-theatre
E	Executive (NPI Department)	4	Car air conditioners, radiators, and engine electrical control units.
F	Senior Manager (NPI Division)	20	2-way radio, mobile phone

The questions required evaluators' assessment on the aspects of relevance, comprehensiveness, coherence, practicality and recommendation; where evaluators provide opinions, comments and additional information.

Evaluators confirmed the three product characteristics as representing the components of the product under validation. The response establishes the relevance of the product characteristics as the basis for the new non-conformance classification. Evaluator B claimed to have an "*almost similar approach*" in describing product characteristics which are known as the *'three components or triangle'*, which represents (i) actual part, (ii) drawings, and (iii) part number. Nonetheless, he recommended the three key product components be put forward in the new classification. Evaluator F suggests each item of product characteristics be validated also for its reliability. Since this research focuses on the quality inspection only, reliability testing is not related to the subject being addressed.

Evaluators agreed that this is a coherent and practical classification in identifying non-conformances resulting from mistakes. Evaluator A claimed about 70% of non-conformances are originated from mistakes, while evaluator B admitted that mistakes are a major source of non-conformances. Evaluator C now had a 'positive' perception on non-conformances rather than 'hating' them, and suggests to his subordinates to look into them seriously during design stage. Evaluator F agreed that mistakes cause non-conformances, but perceived other elements also contribute, such as process variation and capabilities which is beyond the scope of this report.

Although evaluator A is sceptical of the practicality of the PNC, which have not been tested in an actual pre-production setting, however evaluator A understands that it is somewhat difficult to test new ideas in sensitive and critical areas in any well established companies. Evaluator C admitted to realising the importance of addressing non-conformances during development, and suggested that the PNC is about ‘risk management’. Evaluator D recommends the concept be used beyond pre-production, especially during design stage. Overall, evaluators perceived the PNC as relevant and recommended for used in pre-production.

In general, evaluators claimed that the new classification is *“categorically correct in defining non-conformance”* and *“it is simple to understand”*. The illustration and description of the classification is agreed, and provides a broader view and clearer picture of non-conformances. All six evaluators agreed that overall the PNC in product validation process were relevant, comprehensive, coherent and practical classification, and recommended in pre-production.

DISCUSSION AND CONCLUSION

This paper has addressed non-conformances in pre-production stage of product design and development. Three aspects have been identified to facilitate product validation and aid the pre-production team in product assessment i.e. mistakes as a major source of non-conformances, the characteristics of product under validation, and the classification of three types of non-conformances. A new classification of non-conformances based on the manifestation of mistakes related to the product characteristic has been presented. The classification has been demonstrated in the actual industrial cases of non-conformances of consumer electronic product. The evaluations have proven to be feasible in defining and identifying non-conformances. It has been shown that it is possible to build a comprehensive understanding of non-conformances by linking the source of non-conformances and product characteristics. Understanding this relationship enable to control and prevents non-conformances from leaving the pre-production. Using a structured procedure, guidelines and appropriate tool, the implementation of the PNC has the potential to provide improved validation practices and rapid rectification of non-conformances.

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