
**Applications of statistical and related
methods to new technology and
product development process —**

**Part 8:
Guidelines for commercialization and
life cycle**

*Application des méthodes statistiques et des méthodes liées aux
nouvelles technologies et de développement de produit —*

Partie 8: Lignes directrices pour la commercialisation et le cycle de vie



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 8, *Application of statistical and related methodology for new technology and product development*.

A list of all parts in the ISO 16355 series can be found on the ISO website.

Introduction

Quality Function Deployment (QFD) is a method to assure customer or stakeholder satisfaction and value with new and existing products by designing in, from different levels and different perspectives, the requirements that are most important to the customer or stakeholder. These requirements are well understood through the use of quantitative and non-quantitative tools and methods to improve confidence of the design and development phases that they are working on the right things. In addition to satisfaction with the product, QFD improves the process by which new products are developed.

Reported results of using QFD include improved customer satisfaction with products at time of launch, improved cross-functional communication, systematic and traceable design decisions, efficient use of resources, reduced rework, reduced time-to-market, lower life cycle cost, improved reputation of the organization among its customers or stakeholders.

This document demonstrates the dynamic nature of a customer-driven approach. Since its inception in 1966, QFD has broadened and deepened its methods and tools to respond to the changing business conditions of QFD users, their management, their customers, and their products. Those who have used older QFD models will find these improvements make QFD easier and faster to use. The methods and tools shown and described represent decades of improvements to QFD; the list is neither exhaustive nor exclusive. Users should consider the applicable methods and tools as suggestions, not requirements.

This document is descriptive and discusses current best practice; it is not prescriptive by requiring specific tools and methods.

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Applications of statistical and related methods to new technology and product development process —

Part 8: Guidelines for commercialization and life cycle

1 Scope

This document describes after optimization of product design to address non-functional requirements, for example, test, produce, commercialize, deliver, support, and eventually retire a product from the market and provides guidance on the use of the applicable tools and methods. The goal is to identify and assure key processes and measures in order to satisfy and deliver value to customers and stakeholders. The topics in this document are not exhaustive and vary according to industry, product, and markets. They are considered a guide to encourage users of this document to explore activities needed to accomplish the same goal for their products.

NOTE Some of the activities described in this document can be used at an earlier stage.

Users of this document include all organization functions necessary to assure customer satisfaction, including business planning, marketing, sales, research and development (R&D), engineering, information technology (IT), manufacturing, procurement, quality, production, service, packaging and logistics, support, testing, regulatory, business process design, and other phases in hardware, software, service, and system organizations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16355-1:2015, *Application of statistical and related methods to new technology and product development process — Part 1: General principles and perspectives of Quality Function Deployment (QFD)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16355-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

4 Basic concepts of QFD

The basic concepts of QFD are described in ISO 16355-1:2015, Clause 4.

5 Integration of QFD and product development methods

5.1 QFD support for product development methods

QFD support for product development methods is described in ISO 16355-1:2015, 5.1.

5.2 Flow of product development with QFD

The flow of QFD methods and tools varies according to the organization and project requirements. Typically, they begin with broad concerns and through prioritization flow down to specifics.

[Figure 1](#)^[1] shows the flow of product development from quality to technology to cost to reliability deployments. This document begins with components deployment and describes additional analyses that are used in new product development.

5.3 Customers and stakeholders

Stakeholders include external customers and internal members of business and work processes who are also important in development of new products, services, information systems, and processes.

6 Types of QFD projects

QFD projects encompass new developments, as well as generational improvements to existing products. The types of QFD projects are described in ISO 16355-1:2015, Clause 6 and ISO 16355-2:2017, Clause 6 Notes.

7 QFD team membership

7.1 QFD uses cross-functional teams

Cross-functional teams are described in ISO 16355-1:2015, 7.1.

7.2 Core team membership

Core team membership is described in ISO 16355-1:2015, 7.2.

7.3 Subject matter experts

Subject matter experts involvement is described in ISO 16355-1:2015, 7.3.

7.4 QFD team leadership

QFD team leadership is described in ISO 16355-1:2015, 7.4.

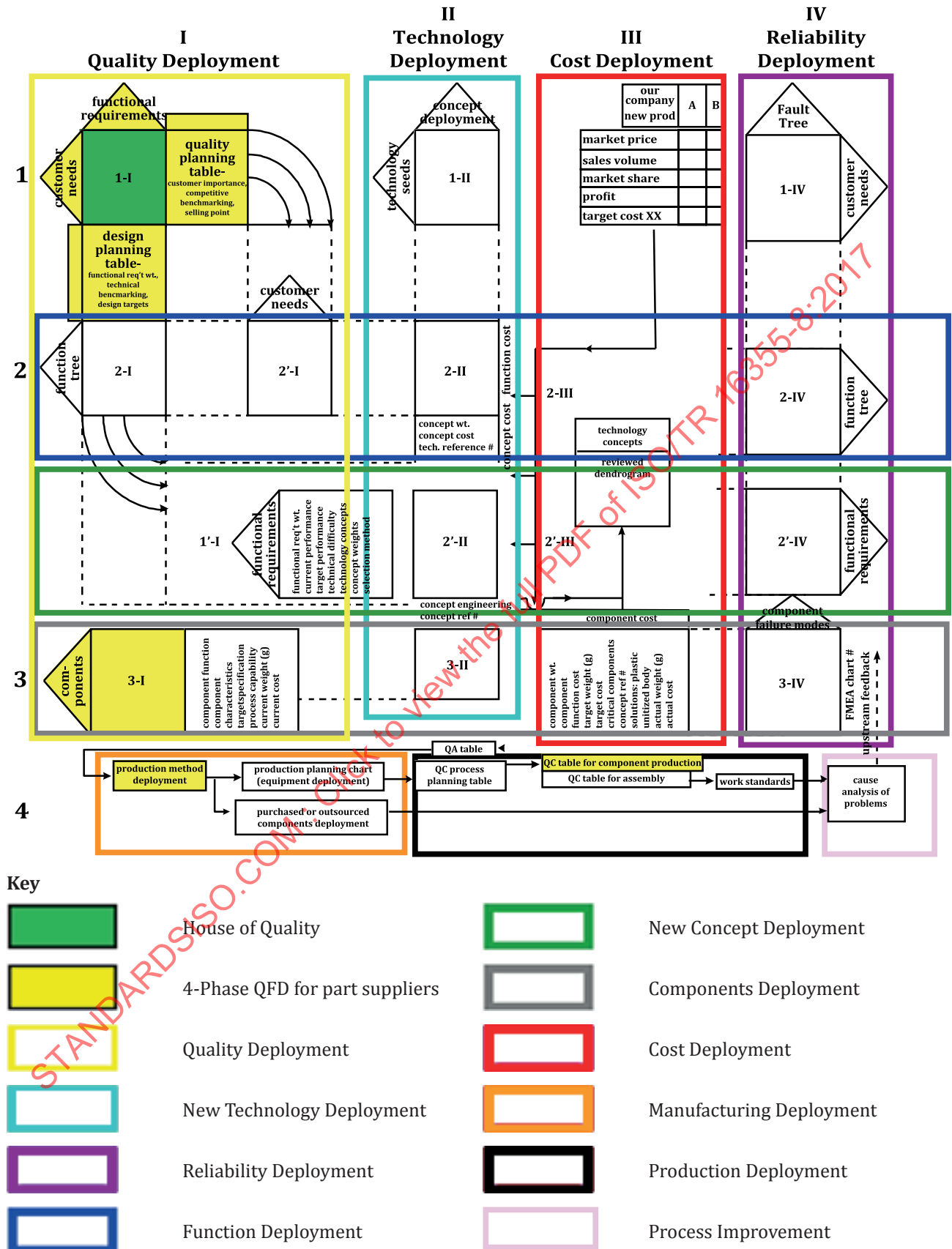


Figure 1 — Comprehensive QFD

8 Lifestyle and emotional quality deployment

While QFD focuses on the functional and performance factors of a product, lifestyle and emotional quality deployment focuses on non-functional factors such as aesthetics, attraction, and sensory responses to a product, its packaging, and its branding. Many products from fashion to industrial products can convey pride in ownership through these factors that lead to brand loyalty, repurchase, and recommendation to others. Consideration of these factors early in the design phase can lead to individualistic configurations that address customer lifestyle and emotions with little cost impact to the maker. One approach that has been long integrated into the QFD process is called Kansei engineering^[30].

8.1 Kansei engineering

Originally developed as a human factors approach to engineer an appealing product by addressing how people interpret inputs from the five physical senses of sight, sound, taste, touch, and smell, Kansei engineering now bridges the traditional industrial design, marketing, and engineering functions^[6]. Lifestyle deployment uses the following steps:

- a) set product image strategy;
- b) identify stakeholders and customers;
- c) visit customers to understand context of use;
- d) interview and do ethnographies to understand customer lifestyle and self-image;
- e) derive lifestyle words with a customer lifestyle table;
- f) have target customers create an affinity diagram to structure lifestyle words and extract product meta-metaphor;
- g) make a hierarchy diagram translating lifestyle words into the five senses;
- h) identify product attributes and set up experimental trials;
- i) have customers quantify lifestyle words with product samples and images; conduct statistical analyses of which design attributes best explain customer lifestyle words;
- j) deploy to design and development.

8.2 Setting product image strategy

Product image should support the brand strategy of the organization. Brand strategy, as with other strategic initiatives, is described in ISO 16355-2. It should consider trends in market and sales, technology, fashion and style, and other preferences.

8.3 Identifying stakeholders and customers

Brand strategy is customer specific according to such demographics as age, sex, culture, geography, occupation, and other factors. The customer segments table described in ISO 16355-2 can be modified to include these factors.

8.4 Visiting customers and stakeholders to understand context of use

Lifestyle is communicated through words, behaviour, body language, and physiological responses. The gemba visit team should include industrial and fashion design, marketing, brand management, retail sales, merchandising, and engineering. Setting up and conducting customer gemba visits where they work and play are described in ISO 16355-2. The gemba visit table described in ISO 16355-2 can be modified to clarify emotional and lifestyle words such as beautiful, powerful, cute, and elegant.

8.5 Interviewing and doing ethnographies to understand customer lifestyle and self-image

Customers and stakeholders are interviewed to discuss their lifestyle choices, preferences, aspirations, motivations, and other matters related to how they wish to appear to others and how they think about themselves. Depending on who the customer is, what his or her peer group values, what advertising message is conveyed (direct ads, product placement in movies, etc.), fads and favourites are constantly changing, creating opportunities for new product excitement and differentiation. Ethnographies help understand the values, beliefs, wishes, dreams, self-image, projected image, future, past cultural positives and negatives about the targeted segment. This psychological profile of the segment is dynamic, and ethnographies are updated frequently to keep information fresh.

EXAMPLE Sample ethnography questions for lifestyle deployment for office wear.

- a) What is your biggest opportunity, concern, challenge, difficulty?
- b) Who in your life do you relate to most? Who is your favourite politician or movie star?
- c) What event in the last 6 months has affected you the most?
- d) What does your clothing say about you?
- e) What clothing article do you care most about and why?
- f) How much time do you spend selecting clothes?
- g) What brands do you like to buy and why?
- h) How long do you usually wear clothes in terms of hours, seasons, years?

8.6 Deriving lifestyle words with a customer lifestyle table

The gemba visit table clarifies lifestyle items and ethnographic responses should then be arranged in a customer lifestyle table (CLT), as shown in [Table 1](#). The CLT attempts to parse and make sense of the somewhat random language in the ethnographies and translate them into lifestyle words^[27].

Table 1 — Customer lifestyle table for office wear

I am a [who] going to [where] in the [when] because I like to [what activity] because it makes me feel [why]; so I want [how product fulfils], and therefore I usually buy [which brand].

Who	Where	When	What activity	Why	How product fulfils	Which brand	Lifestyle words
Urban Uptown, Money and Brains	Work at the client's place of business	Year-round	I like to lead people and projects.	Many years of experience have led to prominence in my field. I am respected and expected to teach others.	My clothing should be subtle and distinctive. My ties should exude power without pretension.	Therefore I buy Kenneth Cole.	Leader, experienced, prominent, smart, respected, teacher, power, subtle, distinctive

8.7 Affinity diagram of lifestyle words

The affinity diagram process is described in ISO 16355-4. Additionally, the affinity diagram should include a meta-metaphor statement that describes the most abstract lifestyle or emotional ideal. This ideal is sometimes used as an advertising tagline.

EXAMPLE Mazda Motor Corporation™¹⁾ in the design of the MX-5 (Miata) employed the meta-metaphor “horse and rider as one” to personify that the automobile was a natural extension of the driver’s mind and body and that they performed as if a single organism.

8.8 Hierarchy diagram of lifestyle words

The hierarchy diagram process is described in ISO 16355-4. In lifestyle deployment, the hierarchy diagram is inserted into a table that includes the sensory organ affiliated with the lifestyle word and the product system or subsystem and the design elements and quality characteristics of the components that interface with the sensory organ. After the analysis is completed, a target performance value or specification for characteristics of the component is added.

EXAMPLE Table 2 shows the flow of information from the meta-metaphor to the sensory organ to the pen system, design, and quality characteristics. In the lifestyle domain, “Words that draw attention” is the desired image of the target customer (engineering consultant) who wants to be seen by her clients as elegant, responsive, and sophisticated. Her pen should be beautiful, well designed, yet warm and curvy. These lifestyle words are sensed through sight and touch. The physical domain includes pen systems such as the body and clip, with design elements and quality characteristics of body dimensions such as length of pen and clip design such as clip materials.

Table 2 — Lifestyle words hierarchy diagram for pen

Meta-metaphor	Lifestyle domain			Physical domain			
	Primary	Secondary	Sense	System	Design element	Quality characteristic	Target specification
"Words that draw attention"	elegant	beautiful	sight	body	body dimension	length	
		good design	sight	clip	clip design	clip materials	
		warm	feel	body	body design	body colour	
		curvy	touch	body	body dimension	curvature	
	responsive	feels easy to use	touch	body	balance	centre of gravity	
		looks easy to write with	sight	tip	shape	roundness	
	sophisticated	expensive looking	sight	body	body design	body materials	
		high class	sound	mechanism	protractor/retractor characteristics	audibility of click	
		modern	sight	body	body dimensions	volume (diameter)	
		thick	sight	ink	ink characteristics	optical density	

1) MX-5 (Miata) is the trade name of a product supplied by Mazda Motor Corporation. This information is given for the convenience of the users of this document and does not constitute an endorsement by ISO of this product.

8.9 Identifying product attributes and set up experimental trials

The quality characteristics and the lifestyle words in the hierarchy diagram are used as the product attributes to be tested. The results of the trials are statistically analysed to identify which lifestyle words are preferred by the customers and which product attribute best explains this preference.

NOTE If too many attributes are tested, the effort asked of the customer to evaluate can increase substantially.

8.9.1 Selecting product concepts to be evaluated

Product concepts are evaluated by the customers while experiencing the concepts with the appropriate senses. Concepts can be actual products, images of products, or unrelated products that share similar attributes^[15]. Each product attribute performance level is exhibited at least twice in the selected product concepts.

NOTE If too many concepts are tested, the effort asked of the customer to evaluate can increase substantially.

EXAMPLE [Figure 2](#) illustrates three product attributes (length, volume, colour) at different levels of performance (short-long, thin-fat, and red-blue-black-silver). There are three short pens and six long pens, four thin pens and five fat pens, and two red, two blue, two black, and three silver pens. Pen #1 is long, thin, silver, and so forth.



Figure 2 — Pen concepts and product attributes

8.9.2 Creating survey of concepts and lifestyle words

Customers are asked to evaluate each product concept against each lifestyle word in a survey. Because the lifestyle words are more emotional than functional, a more psychologically friendly survey method, the semantic differential, is recommended^[32]. The semantic differential survey uses polar opposite adjectives along a 5- or 7-level scale, with the upper levels expressing the more desired adjective. The opposite words are antonyms or “not” constructions, with the latter considered a bit more unnatural

sounding but less likely to be misinterpreted. Examples of antonym polar opposites include hot-cold and expensive-cheap. Examples of “not” constructions include hot-not hot and expensive-not expensive.

EXAMPLE 1 The following 10 polar word pairs were used in a semantic differential survey. Customers were instructed to view the sample pens in [Figure 2](#) and respond on a 1 to 5 scale (5 being most desired) according to how they felt about each pen. The results were recorded in a response grid in a statistics app.

1. Beautiful	5-4-3-2-1	ugly
2. Good design	5-4-3-2-1	bad design
3. High class	5-4-3-2-1	low class
4. Modern	5-4-3-2-1	conservative
5. Curved	5-4-3-2-1	straight
6. Thick	5-4-3-2-1	thin
7. Easy to use	5-4-3-2-1	hard to use
8. Easy to write	5-4-3-2-1	hard to write
9. Warm	5-4-3-2-1	cool
10. Expensive	5-4-3-2-1	cheap

EXAMPLE 2 See [Figure 3](#) for the result of a customer's evaluation of pens. For beautiful vs. ugly, the customer felt that pen #1 was a 3 on the 1 to 5 scale, pen #2 was a 2, pen #3 was a 2, pen #4 was a 5, and so forth for each pen and each lifestyle word pair.



1. Beautiful	5-4-3-2-1	ugly	3	2	2	5	1	2	1	4	4
2. Good design	5-4-3-2-1	bad design	5	4	1	4	2	5	2	4	4
3. High class	5-4-3-2-1	low class	3	3	2	5	3	3	2	2	4
4. Modern	5-4-3-2-1	conservative	5	5	3	3	4	5	1	4	3
5. Curved	5-4-3-2-1	straight	2	3	4	4	4	3	5	5	4
6. Thick	5-4-3-2-1	thin	3	4	2	4	5	5	2	5	4
7. Easy to use	5-4-3-2-1	hard to use	4	4	3	4	4	4	1	4	3
8. Easy to write	5-4-3-2-1	hard to write	5	3	3	4	4	4	1	5	2
9. Warm	5-4-3-2-1	cool	4	2	4	5	4	2	3	4	5
10. Expensive	5-4-3-2-1	cheap	4	2	2	5	3	5	4	4	4

Figure 3 — One customer's evaluation of pens per each lifestyle word

8.10 Statistical analysis of customers' evaluations of products

The survey is fielded to pre-qualified customers within the segment identified in 8.3. The sample size of respondents should reflect the confidence intervals as described in ISO 16355-4. All responses are entered into a statistical app worksheet aligned to the attributes in the trials in Figure 2. Statistical analyses include factor analysis, principal component analysis, and bivariate correlations to identify which lifestyle words best reflect the customer's lifestyle, which product quality characteristic best explains the lifestyle word, and which performance level is preferred.

NOTE Survey sample size can be affected by the number of concepts, number of lifestyle words, number of attributes, and number of levels of each attribute. The larger the number of words and levels, the larger the sample needed. Studies with five concepts, five lifestyle words, three attributes at two levels each were conducted with as few as 60 participants.

EXAMPLE 1 In Table 3, the lifestyle words are entered in the columns and evaluations of the nine pens are shown in the rows. To the right of the responses are the trials describing the attributes given in Figure 2. This particular statistical app requires that length be expressed as a 1 for short or 2 for long, as well as a 0 (off) for l1 and 1 (on) for l2 if the pen is long. In this example, pen #1 is long, thin, and silver as indicated in Table 3.

Table 3 — Survey responses for pen entered into a statistical package worksheet

Semantic differential lifestyle words										Length and levels			Volume and levels			Colour and levels				
Beautiful	Good_design	High_class	Modern	Curved	Thick	Easyuse	Easywrite	Warm	Expensive	length	l1 (short)	l2 (long)	volume	v1 (thin)	v2 (fat)	colour	silver	blue	black	red
3	5	3	5	2	3	4	5	4	4	2	0	1	1	1	0	1	1	0	0	0
2	4	3	5	3	4	4	3	2	2	2	0	1	1	1	0	1	1	0	0	0
2	1	2	3	4	2	3	3	4	2	2	0	1	1	1	0	2	0	1	0	0
5	4	5	3	4	4	4	4	5	5	2	0	1	2	0	1	3	0	0	1	0
1	2	3	4	4	5	4	4	4	3	1	1	0	2	0	1	3	0	0	1	0
2	5	3	5	3	5	4	4	2	5	1	1	0	2	0	1	1	1	0	0	0
1	2	2	1	5	2	1	1	3	4	2	0	1	2	0	1	2	0	1	0	0
4	4	2	4	5	5	4	5	4	4	2	0	1	2	0	1	4	0	0	0	1
4	4	4	3	4	4	3	2	5	4	1	1	0	1	1	0	4	0	0	0	1

EXAMPLE 2 The principal components analysis extraction in Table 4 indicates that MODERN has the most variation in common with the other variables. The higher the number in the extractions column, the more communality it has.

Table 4 — Principal component analysis communalities

Communalities		
	Initial	Extraction
Beautiful	1,000	0,827
Good_design	1,000	0,913
High_class	1,000	0,645
Modern	1,000	0,986
Curved	1,000	0,625
Thick	1,000	0,520
Easyuse	1,000	0,977
Easywrite	1,000	0,802
Warm	1,000	0,859
Expensive	1,000	0,762

Extraction Method: Principal Component Analysis.

EXAMPLE 3 A bivariate correlation is run to determine which levels of each quality characteristic best explain MODERN. Table 5 shows that a short (l1), thin (v1), silver pen has the highest correlations to MODERN for the target customer segment.

Table 5 — Bivariate correlation

		modern	l1	l2	v1	v2	silver	blue	black	red
modern	Pearson correlation	1	0,189	−0,189	0,239	−0,239	0,756	−0,714	−0,071	−0,071
	Sig. (2-tailed)		0,626	0,626	0,536	0,536	0,018	0,031	0,855	0,855
	N	9	9	9	9	9	9	9	9	9

8.11 Deploy to design and development

Based on the above analysis, more specific shortness, thinness, and silver variations can be prototyped and further tested with target customers. The use of lifestyle deployment for packaging is discussed in [Clause 15](#).

9 Component deployment

9.1 General

Once the functional and performance requirements of the high level design have been optimized as described in ISO 16355-5, ISO 16355-6, and ISO 16355-7 and non-functional requirements (aesthetics, lifestyle, emotional quality) have been examined as described in [Clause 8](#), the design should continue to be analysed to the component level. A series of L-matrices and tables deploy quality, technology, cost, reliability, and other factors from the high level design to the component level.

NOTE According to the product, components can be specific parts or assemblies of parts from the bill of materials of a physical product^[36], ingredients of a processed food or chemical product, human tasks in a service product, or objects, entities, or lines of code in a software or information technology product.

9.2 Modern Blitz QFD^{®2)} and the maximum value table (MVT)

When using the maximum value table as described in ISO 16355-5, critical components occupy one or more columns. The maximum value table only deploys the design and development of components critical to high priority customer needs.

EXAMPLE Table 6 shows the deployment of toaster functional requirements and characteristics to selection of a quartz heating technology to the critical components of heating elements, conveyor motor, feed ramp, and thermostat. Specifications and performance targets columns are added after testing and confirmation with customers.

Table 6 — Maximum value table for toaster in airport breakfast kiosk

Customer				Analysis	Design				Quality	Project			
Customer characteristics	Customer task	Customer problem	Customer needs	Toaster characteristics	Technology	Parts	Reliability	Manufacturing	QC processes	Cost	Schedule	Skill	Project tasks
Business travellers			I can make a healthy choice	Max feed rate		Heating elements	Contamination during installation	Quartz bulb installation	Surface wipe				Locate quartz toaster vendor
	Business woman changing planes in hub, frowning	"Nothing here looks good."	I can get a taste I like	Toast colour	Quartz heating	Conveyor motor		Wire harness	Air spray			Training in contamination testing	
			I can make an appealing choice	Toast consistency		Feed ramp		Final assembly					
				Feed opening height		Thermostat		Inspection and testing					

9.3 Functional requirements-components matrix

9.3.1 Purpose of the functional requirements-components matrix

This L-matrix identifies which components have a strong relationship with the functional requirements (product characteristics and capabilities). It also records component level quality characteristics and target values, component functions, process capability targets, current component cost, and other factors. The matrix transfers functional requirements priority weights into component priority weights, which helps the QFD team allocate technical resources to components with high value to customers.

NOTE The functional requirements-component matrix is labelled matrix 3-I in the Comprehensive QFD flow chart in Figure 1. If this matrix is done with proportional distribution as described in ISO 16355-5, component target costs can also be calculated. Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this matrix is the second matrix in the series. Readers familiar with the matrix of matrices can recognize this as the A-4 matrix[23].

9.3.2 Building the functional requirements-components matrix

The L-matrix is used for the functional requirements-function matrix. This document follows the convention of using matrix rows for the already-derived information and weights and the columns for

2) Blitz QFD[®] is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

the to-be-derived information and weights. This means that the 3-I matrix in the comprehensive QFD flow chart is rotated 90° counterclockwise, considering the following steps.

- 1) The functional requirements and weights from the columns of the customer needs-functional requirements matrix (house of quality) described in ISO 16355-5 are inserted into the rows. If the weighted design planning table described in ISO 16355-5 is used, the adjusted priorities are used.
- 2) The components at the same level of detail as the functional requirements, usually the tertiary level of detail, are inserted into the columns. Components should be organized into a hierarchy diagram of systems, subsystems, and components.
- 3) Using the cause-to-effect approach and working row-by-row, the strength of the relationship of each component to achieving the functional requirement is determined. The icons and symbols described in ISO 16355-5 are used.
- 4) The priorities of the functional requirements are transferred into priorities for the components following the steps described in ISO 16355-5. If component cost deployment is to be used later, then the proportional distribution is used instead of the independent or ideal distribution when calculating component weights. Optionally, the prioritized components can also be rank-ordered.
- 5) Component characteristics and target specifications are added.

EXAMPLE 1 In ISO 16355-5, the customer needs-functional requirements matrix (house of quality) was introduced for the airport breakfast kiosk service. A bagel toaster was added to improve customer satisfaction with number of heating options. However, standard bread toasters require approximately 6 min to toast a bagel, so a new toaster was required that could toast a bagel in less than 1 min. In Table 7, a toaster house of quality illustrates how customer needs priorities are used to prioritize toaster functional requirements and characteristics with an L-matrix and symbols explained in ISO 16355-5.

Table 7 — Customer needs-functional requirements matrix (house of quality) for toaster in airport breakfast kiosk (ideal distribution)

Toaster Characteristics		Priority	Max feed rate TC1	Toast colour TC2	Toast consistency TC3	Feed opening height TC4
Customer Needs						
I can make a healthy choice		19,3%				
I can get a taste I like		60,6%				
I can make an appealing choice		11,6%				
I can choose quickly		8,6%				
weighted	Absolute Weight		0,143	0,135	0,141	0,020
	Toaster Characteristic Weight		32,6%	30,8%	32,0%	4,6%
	Toaster Characteristic Rank		1	3	2	4

20 bagel halves/minute

Edge to centre colour change less than 2 shades

0,440

100,0%

EXAMPLE 2 The toaster house of quality is then cascaded into Table 8 by rotating the columns into rows and transferring the toaster characteristics into component part priorities and characteristics target specifications following the steps in 9.3.2. These are displayed with an L-matrix and symbols explained in ISO 16355-5.

Table 8 — Functional requirements and characteristics-component parts matrix for toaster in airport breakfast kiosk (ideal distribution)

Component Parts		Priority					
Toaster Characteristics			Heating elements	Conveyor motor	Feed ramp	Thermostat	
			P1	P2	P3	P4	
TC1	Max feed rate	32,6%					
TC2	Toast colour	30,8%					
TC3	Toast consistency	32,0%					
TC4	Feed opening height	4,6%					
weighted	Absolute Weight		0,977	0,486	0,208	0,266	1,937
	Component Parts Weight		50,4%	25,1%	10,8%	13,7%	100,0%
	Component Parts Rank		1	2	4	3	

Target Value

2,5KW

9.4 Component-sub-function matrix and value engineering

9.4.1 Purpose of the component-sub-function matrix

The purpose of the component-sub-function matrix is to set up a value engineering study to identify and eliminate high component costs and poor performance based on functions (what the component does) versus how it is made. The goal is to improve performance with reduced cost. QFD matrices add customer needs and weights to engineering perspectives as a driver of the calculations of component performance, function, and cost ratios.

9.4.2 Building the component-sub-function matrix

- 1) The components from the bill of materials or components build list are inserted into the rows of the matrix. This can differ for processed products (ingredients and additives), services (jobs), and software (objects). Component weights come from the columns of the functional requirements-components matrix explained in 9.3 and shown in Table 10. Since this is used for cost calculations, the ratio scale weights and proportional distribution described in ISO 16355-5 are used.
- 2) A component level sub-function tree is built for each component. This is done by examining the functions of each component. The function tree is inserted into the columns of the component-sub-function matrix to the most detailed level.

EXAMPLE 1 Table 9 is an example of a function tree deployed to three levels. Steps for building a function tree are described in ISO 16355-5. Here, the primary level function of the master cylinder is to locate components, the secondary level function is to hold parts and affix parts, and the tertiary functions include hold fluid, hold pressure, attach body on vehicle, and so forth. The table has been truncated for confidentiality[11].

Table 9 — Component function tree for vehicle brake master cylinder (partial)

Locate components	Hold parts	Hold fluid
		Hold pressure
	Affix parts	Attaches body on vehicle
		Attaches reservoir cover
		Attaches reservoir gasket

- 3) The relationships between the sub-functions and the components, working row-by-row, are examined. Since this is used for cost analysis, the full nine levels and the ratio scale values described in ISO 16355-5 are used for the relationship weights.
- 4) The component weights are transferred to the sub-function weights using the proportional distribution method described in ISO 16355-5 since this is used for cost analysis.

EXAMPLE 2 [Table 10](#) shows a truncated view of the calculation of component part weights. Functional requirement weights are calculated in the customer needs-functional requirements matrix (house of quality) which is not shown here due to confidentiality^[11]. One functional requirement, master cylinder (MC) weight (mass), has relationships to many component parts, including the warning label, which is discussed below. The functional requirement weight is transferred to the component part weights, which is 0,01 or 1 %.

Table 10 — Functional requirements-component matrix for vehicle brake system

		Component parts	Master cylinder body	Clamp	Clamp screws	Lever	Pivot pin	Bushing (lever pin)	Retaining ring (lever)	Sight glass	Cover gasket	Cover	Warning label
Physical	Lever	Ratio				●							
		Width				●							
Other		Resistance lever apply force				●	○	◐					
		Master cylinder weight	●	◐	○	●	○	○	○	○	○	◐	○
Performance	Lever	Lever force vs travel	●			●							
		Lever dead stroke	●			○							
	System	Force vs pressure	●			●							
		Stroke vs Deceleration (lever)	●			●							
	Other	Lever reach	●			●							
Absolute weight													
Component parts weight												0,01	

EXAMPLE 3 [Table 11](#) partially illustrates the transfer of component weights into sub-function weights. These are displayed with an L-matrix and symbols explained in ISO 16355-5. [Table 11](#) has been truncated for confidentiality and does not show the calculated weights^[11].

Table 11 — Component-sub-function matrix for vehicle brake master cylinder (partial)

Sub-functions \ Component parts	Hold fluid	Hold pressure	Attach body to vehicle	Attach reservoir cover	Attach reservoir gasket	Attach clamp	xxxxxx	yyyyyy	Position spring	Position lever	Position part timing	Position wiper	Flow uni-directional	Create pressure	Feedback output	Input for hand	Flow fluid bi-directional	Vent air	Push piston	Amplify input
Master cylinder body	●	●	●	●	●	●	●	●		●	●	●		●	●		●			
Clamp			●												●					
Clamp screws			●			●									●					
Lever										●	●			●	●	●			●	●
Pivot pin										●	○			○	●				○	
Bushing (lever pin)											○			○	○				○	
Retaining ring (lever)																				
Sight glass		○																		
Absolute weight																				
Sub-function weight																				

NOTE xxxxx and yyyyy represent confidential information.

9.4.3 Value analysis (VA)

The purpose of value analysis is to put cost into areas that have the most value to the customer or stakeholder. Value analysis takes the percentage cost of each component based on total system component cost and examines its ratio to the value of the component calculated in the functional requirements-component matrix. A ratio of 1 would be a component with equal cost and value. The purpose of VA is to identify components where the ratio is greater than 1, indicating that the cost of the component is greater than the value the component provides.

EXAMPLE In the vehicle brake system, the warning label has a high cost to value ratio of 66,06, which is calculated by taking the cost of the warning label/total cost of all parts which is 0,66 % (actual costs are not shown, just the ratio). The value of the warning label is the component part weight for the warning label which is 0,01 as shown at the bottom of Table 10. The value ratio is then calculated as $0,66/0,01 = 66,00$ rounded to two decimal places. Each component cost to value ratio is plotted as a line graph as shown in Figure 4 where each dot indicates a component. Dots above the 45° line indicate the component cost exceeds its value and efforts are made to reduce the cost or increase the functionality of the component through value engineering where the goal is to achieve a target cost and value ratio of 1. The value analysis can also be displayed per component in a bar chart as shown in Figure 5[1].

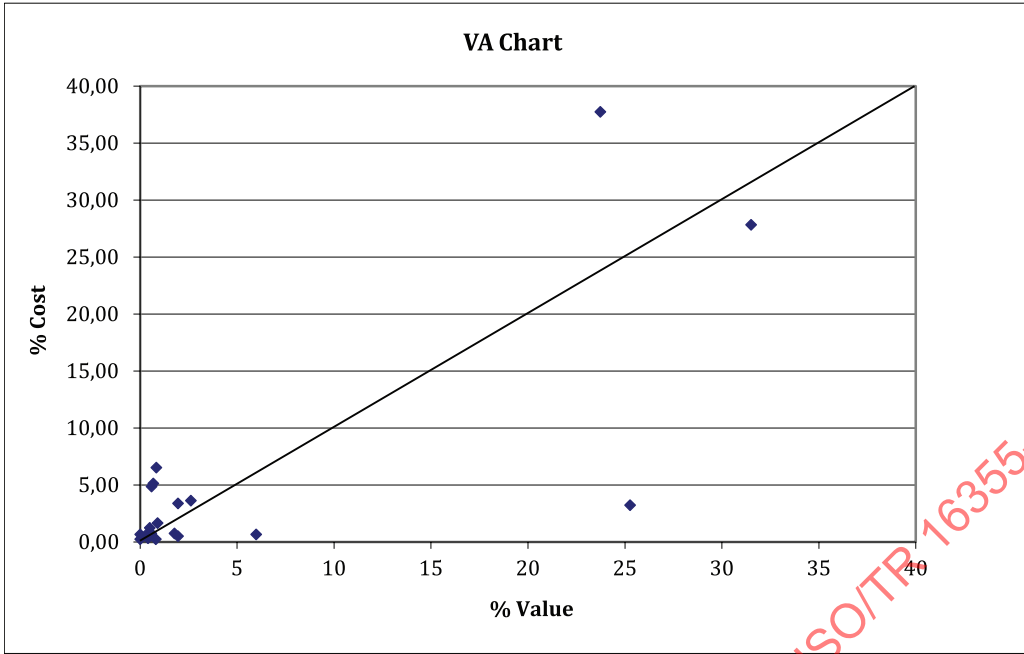


Figure 4 — VA chart showing % component cost against % value of component to system

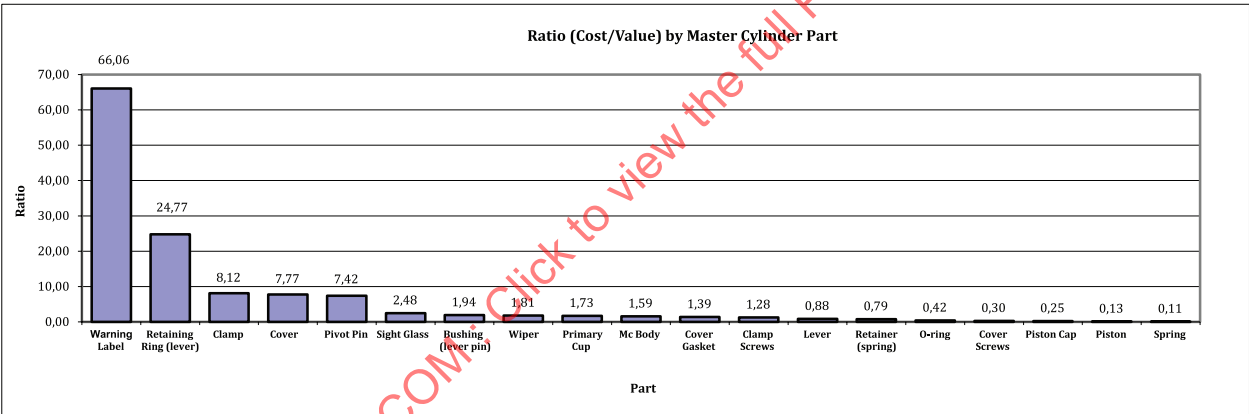


Figure 5 — VA bar chart showing value ratio of each component

9.4.4 Value engineering (VE)

Value engineering (VE) is one way to increase the functionality of components. The VE analysis takes the percentage cost of each component based on total system component cost and examines it against the percent of function it provides in the system as determined in the component-sub-function matrix in 9.4.1. A ratio of 1 would be an equal cost/function percentage. Components with a ratio greater than 1 are investigated for adding functions or combining its functions into other components.

EXAMPLE In the vehicle brake system, one proposal was to mould the warning label into the cover of the master cylinder which would combine functionality into one part and reduce the per-piece cost of having two parts.

NOTE The value engineering community uses additional techniques such as function analysis system technique (F.A.S.T.) diagrams. These diagrams build on the function trees shown in Table 9, but do not have the customer-driven weights that QFD provides[38].

9.5 Function-subassembly and component matrix

9.5.1 Purpose of the function-components matrix

Another approach used to improve component performance and function and reduce cost is this L-matrix which identifies which components have strong relationships with product functions. This is useful in developing product modularization and platforms^[14]. The purpose is to look for customer-driven product variations that can share an internal interface in a common platform. These product variations address different customer uses and applications.

NOTE This matrix is not included in the 4-phase QFD, comprehensive QFD, or matrix of matrices. It is a more recent analysis often used in the automotive industry.

9.5.2 Building the function-component matrix (unweighted)

The following steps are considered.

- 1) The functions from the function tree described in ISO 16355-5 are inserted into the rows.
- 2) The components from the bill of material are inserted into the columns.
- 3) Using the cause-to-effect approach and working row-by-row, the strength of the relationship of each component to performing the function is determined. The icons and symbols described in ISO 16355-5 are used.
- 4) Functions that are performed with fewer parts are identified. Parts which could be modified to perform more functions are identified.

EXAMPLE In [Table 12](#), function 2 requires three parts. Is it possible to do it with only two parts and eliminate part 4? Similarly, part 1 is required by functions 1, 2, and 4. Could it also do function 3? If both conditions are possible, part 4 could be eliminated.

Table 12 — Function-component matrix (generic)

	Part 1	Part 2	Part 3	Part 4
Function 1	●	○	◐	
Function 2	●	●		◐
Function 3				●
Function 4	◐		●	

9.6 Subsystem-components matrix

9.6.1 Purpose of the subsystem-components matrix

This matrix is used to solve engineering bottlenecks as described in ISO 16355-5. By looking at critical components in a subsystem, it is possible to solve a problem and then look at the impact on quality and cost. Subsystem priorities and costs are then allocated to components using proportional distribution as described in ISO 16355-5.

NOTE The functional requirements-component matrix is labelled matrix 3-II in [Figure 1](#). If this matrix is done with proportional distribution as described in ISO 16355-5, component target costs can more be accurately calculated. Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this matrix is not included. Readers familiar with the matrix of matrices can recognize this as the C-4 matrix^[23].

9.6.2 Building the subsystem-components matrix

The following steps are considered.

- 1) The subsystems from the function-system/subsystem matrix described in ISO 16355-5 are inserted into the rows.
- 2) The components from the bill of materials are inserted into the columns.
- 3) Using the cause-to-effect approach and working row-by-row, the strength of the relationship of each component to the subsystem is determined. The icons and symbols described in ISO 16355-5 are used.
- 4) The priorities of the subsystems are transferred into priorities for the components following the steps in ISO 16355-5. If cost deployment is to be used later, then the proportional distribution is used instead of the independent or ideal distribution. Optionally, the prioritized components can also be rank-ordered.
- 5) The target cost of the subsystems is allocated to the target cost of the components.
- 6) Components that are problematic to the subsystem, such as quality and cost, are identified. Using proportional distribution as described in ISO 16355-5, subsystem costs are transferred to component costs. Actual costs per component are estimated, and ways to bring target and actual cost in line are looked for and investigated.

EXAMPLE Table 13 is a matrix transferring key breakfast kiosk subsystems and costs from the function-system/subsystem matrix described in ISO 16355-5 to the components, which are the products and service tasks in the kiosk. The subsystem target cost of €1,00 is proportionally distributed to the component product and service tasks per the component weights and target costs at the bottom of the matrix. These are displayed with an L-matrix, symbols, and proportional distribution explained in ISO 16355-5.

Table 13 — Subsystem-components matrix for airport breakfast kiosk (proportional distribution)

Component tasks		Subsystem weight	ORDER		STORE		PREPARE		DISPLAY		PAY		Subsystem target cost
			order to inventory levels	rotate inventory	pull oldest first	finish bake bagels	mix toppings	heat bagels	keep display case full	process payment			
Subsystems			Task1	Task2	Task3	Task4	Task5	Task6	Task7	Task8			
INFO	nutrition	7,62%	0,000	0,066	0,011	0,000	0,000	0,000	0,000	0,000	0,000	0,076	
	menu	20,07%	0,062	0,000	0,014	0,000	0,000	0,000	0,125	0,000	0,000	0,201	
ORDERING	order-taking	10,24%	0,000	0,000	0,000	0,000	0,000	0,000	0,102	0,000	0,000	0,102	
	order fulfilment	9,14%	0,000	0,000	0,000	0,017	0,017	0,017	0,008	0,033	0,000	0,091	
PREPARATION	bagels	27,88%	0,081	0,000	0,018	0,162	0,000	0,018	0,000	0,000	0,000	0,279	
	toppings	19,62%	0,061	0,000	0,000	0,000	0,122	0,000	0,014	0,000	0,000	0,196	
DEL	heating	2,78%	0,000	0,000	0,000	0,003	0,000	0,025	0,000	0,000	0,000	0,028	
	utensils	2,66%	0,021	0,000	0,000	0,000	0,005	0,000	0,000	0,000	0,000	0,027	
weighted	Absolute Weight		0,225	0,066	0,043	0,181	0,144	0,060	0,249	0,033	Target cost		1,000
	Component Weight		22,5%	6,6%	4,3%	18,1%	14,4%	6,0%	24,9%	3,3%	1,00		100,0%
	Component Target Cost		0,225	0,066	0,043	0,181	0,144	0,060	0,249	0,033	Component target cost		

9.7 Component-failure mode matrix

9.7.1 Purpose of the component-failure mode matrix

This L-matrix is used to identify subsystem and component level failure modes by looking at critical components in a subsystem. It is used with other reliability methods to solve or prevent the failure modes.

NOTE The component-failure mode matrix is labelled matrix 3-IV in [Figure 1](#). Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this matrix is not included. Readers familiar with the matrix of matrices can recognize this as the D-4 matrix[23].

9.7.2 Building the component-failure mode matrix

The following steps are considered.

- 1) The subsystems or components from the bill of materials are inserted into the rows.
- 2) Failure modes from a component level fault tree as described in ISO 16355-5 are inserted into the columns.
- 3) Working row-by-row, the strength of the relationship between the components and the failure mode is determined using the symbols described in ISO 16355-5.
- 4) The component weights are transferred to the failure mode weights using the independent distribution method described in ISO 16355-5. Note key components for FMEA.

EXAMPLE [Table 14](#) shows the relationship matrix portion. The component and failure mode weights are omitted for confidentiality.

Table 14 — Component-failure mode matrix for flashlight

		Light not focused			
		Uneven light pattern	Cracked reflector	Lens distorted	
				Lens warped	Lens cloudy
Reflector	Substrate	●	●		
	Mirror coating	◐	○		
Lens	Optical elements	●			●
	Rotator	◐		●	
	Holder		◐	●	

9.8 Component failure mode and effects analysis (FMEA)

9.8.1 General

Component failure mode and effects analysis (FMEA) is a qualitative and quantitative analysis of failure modes known from past experiences. It is used as a guide to preventing similar failures in the new product. Here, FMEA is applied at the product, system, subsystem, component, process, and equipment levels (see References [1], [29] and [40]). FMEA helps prioritize which failure modes have the greatest impact on customer satisfaction by analysing the impact failures have on component performance and function. These evaluations are simply verbal as described in ISO 16355-5 or they are quantified.

When quantified, ratio scale numbers for each factor improve the accuracy of the calculation of the risk priority number (RPN).

NOTE FMEA is associated with the components deployment level matrix 3-IV in the Comprehensive QFD flow chart in [Figure 1](#). Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this is not included. Readers familiar with the matrix of matrices can recognize this as the F-2 table[23].

9.8.2 Risk priority number (RPN) calculation

In addition to the detailed information about the nature of the failures recorded in the FMEA table is the prioritization of the failures that focuses the engineering efforts on which failure to resolve first. QFD, through the flow down of customer needs weights to function weights as described in ISO 16355-5 and then to component weights, aids this prioritization process. The FMEA table is then applied to record the analysis of the risk-of-failure components before and after solutions. Risk is a calculation of the impact on the product when the failure occurs, how frequently the failure occurs, and how easy it is to detect the failure when it occurs. Traditional FMEA uses a verbal scale with ordinal numbers assigned to each of 10 levels, and then multiplies the ordinal numbers to calculate the RPN. As discussed in ISO 16355-2 and ISO 16355-4, ordinal scale numbers do not contain sufficient information to perform mathematical functions like +, −, ×, and / due to lack of absolute values and inequality of ratios between the intervals. The accuracy of the RPN calculation is improved by ratio scale numbers, and the analytic hierarchy process (AHP) as described in ISO 16355-2 and ISO 16355-4 is used.

9.8.2.1 Severity of impact of failure (SEV)

Severity of impact of the failure on the product is estimated on a verbal scale and scored in ratio scale as shown in [Table 15](#).

Table 15 — FMEA severity of impact score in verbal and ratio scale scores

Severity	Score
Hazardous/safety effect	1,00
Potential hazard/safety effect, but can be stopped	0,71
Inoperable, but no hazard/safety concern	0,50
Performance severely degraded, but functional	0,34
Performance degraded, but operable	0,24
Moderate performance reduction, can be repaired	0,16
Minor performance reduction, no repair needed	0,11
Slight performance reduction frequently noticed	0,08
Slight performance reduction occasionally noticed	0,06
No effect	0,00

9.8.2.2 Frequency of occurrence

Frequency estimates cumulative failures per 1 000 pieces or transactions[40]. These numbers are recalculated into ratio scale scores as shown in [Table 16](#).

Table 16 — FMEA frequency of occurrence score in numerical and ratio scale scores

Occurrence (cumulative # of failures/1 000 parts/transactions)	Value	Score
Failure almost certain	500	0,494 279
Very high number of failures likely	316	0,312 385

Table 16 (continued)

Occurrence (cumulative # of failures/1 000 parts/transactions)	Value	Score
High number of failures likely	134	0,132 467
Moderately high number of failures likely	46	0,045 474
Medium number of failures likely	12,4	0,012 258
Occasional numbers of failures likely	2,7	0,002 669
Few failures likely	0,46	0,000 455
Very few failures likely	0,006 8	0,000 007
Rare failures	0,006 3	0,000 006
No history of failures	0,000 6	0,000 001
	Σ 1011,6	

9.8.2.3 Detectability

Ease of detection is estimated on a verbal scale and scored in ratio scale as shown in Table 17.

Table 17 — FMEA detectability in verbal and ratio scale scores

Detectability	Score
No detection method known	1,00
Detection method unreliable	0,71
Very low effectiveness of detection method	0,50
Low effectiveness of detection method	0,34
Medium effectiveness of detection method	0,24
Moderate effectiveness of detection method	0,16
High effectiveness of detection method	0,11
Very high effectiveness of detection method	0,08
Extremely high effectiveness of detection method	0,06
Certain detection	0,00

9.8.2.4 Prioritizing factors

Traditional FMEA assumes that severity, frequency of occurrence, and detectability are equally important to the project. It is possible to balance these factors differently using the AHP method^[37] described in ISO 16355-2 and ISO 16355-4.

9.8.2.5 Calculating RPN with AHP

The following steps are considered.

- 1) The severity, frequency, and detectability factors are balanced using AHP. The results are entered in the FMEA table next to each factor.

EXAMPLE 1 In Table 19, the QFD team determined that the severity (SEV), frequency of occurrence (OCC), and detectability (DET) were not equally important and used the AHP grid in Table 18 to determine that in this project, severity is 63,3 % concern, frequency of occurrence is 26 % concern, and detectability is 10,6 % concern. These factor weights are entered in Table 19 in the relative importance of factors area.

Table 18 — RPN factor weighting with AHP for flashlight

RPN factor weight	SEV	OCC	DET				sum	row avg
SEV	1	3	5	0,652	0,692	0,556	1,900	0,633
OCC	1/3	1	3	0,217	0,231	0,333	0,781	0,260
DET	1/5	1/3	1	0,130	0,077	0,111	0,318	0,106
	1,533	4,333	9,000	1,000	1,000	1,000	3,000	1,000
Inconsistency ratio								0,03

- 2) A high priority component and its failure modes are entered into the FMEA table. This is determined from the component-failure mode matrix in [9.7](#).

EXAMPLE 2 From [Table 14](#), the reflector substrate component and uneven light pattern failure mode were selected.

- 3) The initial severity of impact is estimated using the verbal scale and corresponding SEV score entered into the FMEA table. This SEV score is then multiplied by the SEV factor weight to calculate a global SEV score.

EXAMPLE 3 The severity of impact before the improvement was estimated to be “performance degraded but operable” and the corresponding value of 0,24 was entered from [Table 15](#). Since the severity factor was determined to be 63,3 %, these two numbers are multiplied ($0,24 \times 0,633$) to calculate the global severity factor weight of 0,15 entered into [Table 19](#).

- 4) The above step is repeated for frequency of occurrence and detectability.
- 5) The global scores for SEV, OCC, and DET are summed to calculate the RPN.
- 6) High RPN failure modes are addressed first as they are most important to customer satisfaction.
- 7) Solutions to the failure modes are developed and tested until a fix is found. Responsibility and deadline for implementation of the solution are assigned.
- 8) The solution is confirmed to work and a new RPN is calculated. The new RPN is confirmed to be acceptable by the QFD team.

Table 19 — Component FMEA table for flashlight with AHP

Failure mode				Failure mode analysis										Action results									
Part name	Function (process/ task)	Potential failure modes	Potential effect(s) of failure	SEV score	Global SEV	Potential cause(s) of failure	OCC score	Global OCC	Current detection method or controls	DET score	Global DET	RPN (sum global SEV+OCC +DET)	Recommend actions	Responsible person and target completion date	Taken actions	SEV score	Global SEV	OCC score	Global OCC	DET score	Global DET	RPN (sum global SEV+OCC +DET)	
Relative importance of SEV, OCC, DET				0.63	0.63		0.26	0.11		0.11							0.63	0.63	0.26	0.26	0.11	0.11	
Reflector substrate	Support reflective surface	Uneven reflective surface	Uneven light pattern	0.24	0.15	Material: thermoset plastic	0.000006	0.000002	Visual inspection	0.71	0.08	0.23	Change to PVC	R&D, 30 d	Material changed	0.08	0.05	0.000001	0.000000	0.71	0.08	0.13	

9.9 Quality assurance (QA) table

9.9.1 Purpose of the QA table

The QA table is used to improve communications between the design and manufacturing departments. This table is created by both departments to assure key component characteristics are consistently assured, and to describe the impact on customer satisfaction if they are failed.

NOTE The QA table is positioned between components FMEA and production method deployment in [Figure 1](#). Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this table is not included. Readers familiar with the matrix of matrices can recognize this as the G-1 table[23]. The QA table is described in JIS Q 9025:2003, Annex 7[22].

9.9.2 Building the QA table

The following steps are considered.

- 1) Unlike the QFD matrices where one information set is transferred to another, the QFD tables elaborate details about each row item. In the QA table, each row item is a component.
- 2) End product and component characteristics are described.
- 3) Whether component characteristics are critical to function or safety is determined.
- 4) Component characteristic tolerance and expectation are identified.
- 5) The impact on customer if component characteristic cannot be met is identified.

EXAMPLE [Table 20](#) identifies the importance of the toaster heating element producing 2,5 KW of power along the length of the element so that the bagel is consistently toasted and toppings can be spread easily.

Table 20 — QA table for heating element for airport breakfast kiosk toaster

Component name	Product characteristic	Component characteristics	Function/safety	Tolerance	Expected value	Impact on customer satisfaction
Heating element	Toast consistency	Power	F	2,5 KW $\pm$ 0,5 KW	Consistent heat along length of element	Inconsistent toasting reduces spreadability of topping

10 Production method (manufacturing and process) deployment

10.1 General

10.1.1 Objective

The purpose of QFD at the pre-production stages is to assure that quality in the manufacturing and process stages is assured to meet key customer needs, and with ease of manufacturing at minimal costs. Manufacturing and process deployments examine the relationships between manufacturing, production, or other build and implementation methods and equipment and quality, technology, cost, and reliability. Agile, lean, and world class manufacturing activities are also supported. Deployments for service and software can be different.

10.1.2 Composition

As shown in the reliability deployment section of [Figure 1](#) (bottom section), production deployment consists of the following matrices, tables, and charts which transfer priorities from the customer needs to

- a) component manufacturing (see [10.3](#)),
- b) quality control process planning table (see [13.2](#)),
- c) quality control tables (see [13.3](#)), and
- d) work standards (see [13.5](#)).

10.2 Modern Blitz QFD® and the maximum value table (MVT)

When using the maximum value table as described in ISO 16355-5, critical implementation processes occupy one or more columns. The maximum value table only deploys the design and development of processes critical to high priority customer needs.

EXAMPLE [Table 21](#) shows some of the columns related to the number one customer need of “I don’t catch any disease while at the sleep centre”. The manufacturing process must prevent introduction of harmful substances into the air flow to the patient’s lungs. This includes using a sonic sealing process instead of adhesive that could flake off and assuring that the moulded plastic filter housing has accounted for materials shrinkage during the moulding process to ensure that no gaps between the housing and the filter media could allow microbes to pass. Specific moulding process parameters such as melt flow pattern, compressing of the melt and others are critical, as is the filter media pleating and insertion into the housing and the sonic sealing of the housing.

Table 21 — Maximum value table with columns for manufacturing and process factors in a medical filter

Manufacturability	Quality metrics	Process parameter optimization	Production/process capability	Assembly/value stream map
Sonic sealing to prevent introduction of adhesives into air flow, injection moulded [75 % polypropylene (PP) and 25 % low density polyethylene (LDPE)] housing. Injection speed and pressure critical to uniform internal wall thickness.	Moulded part shrinkage is critical for internal diameter of housing for proper sealing of HEPA filter. Die design and wall thickness are very important. Melt flow pattern, compression of melt, land length, back pressure are important factors in die design.	Die design and wall thickness are very important. Melt flow pattern, compression of melt, land length, back pressure are important factors in die design. Optimal combination for low shrinkage. The optimum conditions are injection speed (90 % r/min), melting temperature (240 °C), injection pressure (110 bar), holding pressure (96 bar), holding time (5 s), and cooling time (10 s).		Filter media pleating, filter media insertion into housing, sonic soldering of housing 

10.3 Components-manufacturing operations matrix

10.3.1 Purpose of the components-manufacturing operations matrix

This L-matrix is used to prioritize manufacturing operations and determine if existing manufacturing operations and equipment constraints can achieve desired component characteristics without the need for new facilities. The matrix also identifies key operating parameters and control points.

NOTE The components-manufacturing operations matrix is labelled production method deployment in [Figure 1](#). Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this is matrix III. Readers familiar with the matrix of matrices can recognize this as similar to the G-2 equipment deployment table [\[23\]](#).

10.3.2 Building the components-manufacturing operations matrix

The following steps are considered.

- 1) The components and their weights from the functional requirements-components matrix in [9.3](#) are inserted into the rows.
- 2) The manufacturing operations necessary to build the components are inserted into the columns.
- 3) Using the cause-to-effect approach and working row-by-row, the strength of the relationship of each manufacturing operation to achieving the component quality is determined. The icons and symbols described in ISO 16355-5 are used.
- 4) The priorities of the components are transferred into priorities for the manufacturing operations following the steps described in ISO 16355-5. Optionally, the prioritized components can also be rank-ordered.
- 5) Manufacturing equipment and operating parameters and control points are added for each manufacturing operation.

EXAMPLE [Table 22](#) shows that the quartz bulb installation is most critical to fulfilling the characteristics for the heating element and must remain oil free.

Table 22 — Components-manufacturing operations matrix for airport breakfast kiosk toaster

Manufacturing Operations									
Component Parts									
Priority									
			Metal working	Quartz bulb installation	Wire harness	Motor mounting	Conveyor installation	Final assembly	Inspection and testing
			M01	M02	M03	M04	M05	M06	M07
P1	Heating elements	50,2%							
P2	Conveyor motor	24,4%							
P3	Feed ramp	10,4%							
P4	Thermostat	15,1%							
weighted	Absolute Weight		0,104	0,502	0,383	0,244	0,244	0,387	0,394
	Manufacturing Operation Weight		4,6%	22,2%	17,0%	10,8%	10,8%	17,1%	17,5%
	Manufacturing Operation Rank		7	1	4	5	5	3	2
			2,257						
			100,0%						
Equipment			Stamping press	Manual insertion	Manual insertion	Torque wrench	Manual	Manual	Multimeter
Process Control Points			Dimensional tolerance: + / - 0,1 %	Must remain oil-free	Pull-apart force > 2 N	Mounting bolt torque: 1,5 N·m	Conveyor deflection < 1 mm	Confirm all assembly hardware	Electrical specifications within 0,1 %

11 Testing, validation, design review, and prototyping

11.1 General

High priority characteristics, parameters, functions, and other design and development dimensions are tested for customer acceptance, human factors/usability, efficacy, regulatory compliance, manufacturability, reliability, safety, and other factors. Deployments for service and software can be different.

11.2 Testing

11.2.1 Purpose of components-test matrix

The purpose of this chart is to evaluate how well a test checks the performance of a component quality characteristic. For incremental product upgrades where only a few components are changed, historical difficulty regarding testing of unchanged parts is identified to help in prioritizing new tests.

NOTE The components-test matrix is not included in Figure 1, the 4-phase QFD, the matrix of matrices, nor the HS Q 9025. It has been useful in the automotive industry where extensive testing for durability and safety is required.

11.2.2 Building the components-test matrix

The following steps are considered.

- 1) The components to be tested are inserted into the rows of the matrix. Component priorities come from the functional requirements-components matrix in 9.3.
- 2) The tests required by the company, customer, stakeholder, or regulatory body for the components are inserted into the columns.

- 3) Using the cause-to-effect approach and working row-by-row, the strength of the relationship of each test to achieving the component quality characteristics is determined. The icons and symbols described in ISO 16355-5 are used.
- 4) The priorities of the components are transferred into priorities for tests following the steps described in ISO 16355-5. Optionally, the tests can also be rank-ordered.
- 5) Historical difficulty in achieving the test specifications is noted.

EXAMPLE [Table 23](#) identifies which component tests are most critical to component performance of the toaster. High temperature resistance is of great concern due to the change in heating element from a filament to a quartz lamp.

Table 23 — Component-component characteristics test matrix for airport breakfast kiosk toaster

Tests			Priority	Tests						
Component Parts				Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7
P1	Heating elements	50,4%								
P2	Conveyor motor	25,1%	0,504	0,251	0,251	0,119	0,000	0,119	0,504	
P3	Feed ramp	10,8%	0,251	0,000	0,059	0,028	0,251	0,251	0,125	
P4	Thermostat	13,7%	0,000	0,000	0,000	0,000	0,108	0,012	0,012	
weighted	Absolute Weight		0,755	0,388	0,379	0,285	0,391	0,451	0,779	
	Test Weight		22,0%	11,3%	11,1%	8,3%	11,4%	13,1%	22,7%	
	Test Rank		2	5	6	7	4	3	1	
Historical difficulty			no difficulty	extremely difficult	difficult	no difficulty	no difficulty	moderately difficult	extremely difficult	

11.3 Validation

11.3.1 General

Validation with objective evidence confirms the product meets customer and stakeholder needs, including quality and reliability concerns.

11.3.2 Focus groups

Focus groups as described in ISO 16355-2 are convened to review the product prototype and confirm market acceptability.

11.3.3 Kano surveys

Kano model surveys as described in ISO 16355-5 are repeated to confirm that function, feature, and performance levels meet exciting and expected levels of satisfaction.

11.3.4 Conjoint analysis

Statistical methods such as conjoint analysis are conducted to confirm feature package and price point levels^[16].

11.4 Design review

QFD team members representing all critical departmental functions including marketing, engineering, implementation and manufacturing, support and others should conduct a formal, documented, comprehensive, and systematic review to confirm the product adheres to design requirements. Quality problems predicted for production are examined and solutions are proposed for any problems discovered. Design reviews are conducted at different stages in the development process.

- a) Planning stage design review is conducted after the transfer of customer needs to functional requirements such as the house of quality as described in ISO 16355-5.
- b) Prototype drawing and pre-production stage design review is conducted to assure design meets functional requirements including quality, reliability, and impact on environment, and subsequently customer and stakeholder needs as identified in prior QFD matrices and tables.
- c) Production stage design review is conducted to assure that manufactured or outsourced components and their assembly meet functional requirements and subsequently customer and stakeholder needs as identified in prior QFD matrices and tables.

NOTE Design review is described in JIS Q 9025:2003, 7.3[22].

11.5 Prototyping

Prototype components, build, and assembly processes are refined to assure the products are successfully built and satisfy customers. In QFD, prototypes are used to confirm that the design is correct and not just to troubleshoot.

12 Production planning

12.1 General

Build planning (manufacturing and pre-production planning, quality planning, pre-launch control plan, service planning, software architecture, and other planning activities) is linked to the design plan, procurement and supply chain management, process flow charts, process validation, material handling and storage, equipment and tooling, and floor plan layout.

Equipment and facilities needed to build systems, subsystems, and components are investigated for critical performance, functionality, quality capabilities that meet or exceed their specifications, process parameter optimization, and process capability studies.

Make-or-buy decisions, as well as supplier qualification, production part approval plan (PPAP), and supplier quality assurance, are done. Periodic critical component supplier assessment visits may also be done. Deployment for service and software can be different. Critical component manufacturing operations are reviewed for process capability and optimal operating conditions[41].

12.2 Process capability

Process capability and performance studies based on current products are conducted to assess how consistently repeatable a process can meet component specifications. Suppliers may also be asked to submit process capability studies[5]. Process capability is explained in ISO/TR 10017[21].

12.2.1 C_p

The process capability index C_p describes how the allowable tolerance is spread between the upper and lower specification limits. The higher the number, the tighter the tolerance is around the specification.

12.2.2 C_{pk}

C_{pk} simultaneously describes both the spread and the shift in the mean value of the process.

12.3 Optimize process

Component process design is made robust to controllable and uncontrollable process conditions or control factors. Optimization calculations are explained in ISO 16355-6 and ISO 16355-7. The goal is to produce the most optimal functional requirements with minimum variation. An efficient investigation should test a subset of control conditions, called an orthogonal array.

EXAMPLE In [Table 24](#), controllable production conditions such as flour protein level, yeast type, and yeast level are combined with uncontrollable process conditions such as water temperature and age of wheat flour (wheat moisture evaporates with age). An L-4 type orthogonal array identifies four combinations of controllable and uncontrollable conditions to test. Taste panel results are averaged ($\bar{y}$) and variance calculated (σ^2). For consistently good bagels, the following recipe is recommended.

- 12,5 % flour protein gives highest average taste evaluation and lowest variance.
- Liquid and dry yeast yield equal average taste evaluation but liquid has lowest variance.
- Doubled normal yeast quantity gives highest average taste evaluation and lowest variance.
- 12,5 % flour protein, liquid yeast, 2× quantity are recommended.

Table 24 — Optimization of process conditions for airport breakfast kiosk bagels

Trial # (L4)	Controllable			Uncontrollable (noise)				$\bar{y}$	σ^2
	Flour type: protein 12,5 % or 14 %	Yeast type: liquid or cream	Yeast level: 1× or 2×	Water 65 °F	Water 45 °F	Water 65 °F	Water 45 °F		
				Old wheat	Old wheat	New wheat	New wheat		
1	12,5 % 1	liquid 1	1 × 1	3,2	3,8	4,5	4,2	3,9	0,18
2	12,5 % 1	dry 2	2 × 2	3,5	3,6	5	4,8	4,2	0,46
3	14 % 2	liquid 1	2 × 2	2,7	3,2	3,8	3,8	3,3	0,19
4	14 % 2	dry 2	1 × 1	2,3	2,6	3,9	4	3,2	0,58
Taste panel evaluations 1–5 scale									

12.4 Make-or-buy decision

Based on equipment availability and process capability, the decision to produce or outsource components is made. Where multiple vendors exist, vendor selection is made using the analytic hierarchy process (AHP) described in ISO 16355-5 for technology selection[2].

EXAMPLE Based on the decision to use par-baked bagels and supplier capability studies, the following specifications were made (see [Table 25](#)).

Table 25 — Specifications to supplier for airport breakfast kiosk bagels***Bagel specifications******Specification to bagel supplier*****Frozen dough characteristics**

Bagel is par-baked and frozen.

Bagel thaws quickly and is oven-ready.

Finish baking requirements

Bagel takes 6 min to finish in oven.

Bagel is hot and fresh from oven.

Bagel allows you to produce to business demands.

Bagel has a consistent quality day to day.

Bagel flavours

Bagels come in four to six flavours: Mandatory flavours are plain, onion, raisin and honey wheat.

Bagels come in two flavours of the month.

Shelf life

Bagel has frozen shelf life of 6 months.

Bagel has refrigerated (un-finished bake) shelf life of 2 d.

12.5 Project work or task management

Project work or task management concerns related to managing resources, skills, tools and testing, cost, milestone and prototypes schedules, risks, changes to scope and schedule, and other areas of project management are examined. It is important that critical-to-schedule tasks such as laboratory testing and others that require advance scheduling to be identified are scheduled as soon as possible so as not to cause later delays in the product development process.

EXAMPLE 1 [Table 26](#) breaks down several project tasks (what) into responsibility (who), timing (when), locations (where), in what way (how), to what quality level (how much), for what reason (why), and other concerns such as possible failure modes if not done in a quality way.

Table 26 — Task management table for airport breakfast kiosk

What	Who	When	Where	How	How much	Why	Other
Finish-bake bagels	Mike Galvin T-4 associate	By Aug. 28	In house	Test equipment	Until comfortable, but no less than 12 batches	Specs for baking method	Failure modes: safety speed of service issues
Order bagel baker	Joe Campbell	By Aug. 25	In house	Purchase order	At least three for each testing unit plus one backup	For start of project in unit	Study failure modes and diagnostics
Order topping scoops	Joe Campbell	By Aug. 23	In house	Test order	Six of each for each test unit	Different types of toppings, portion control, speed of service	Possible equipment other than scoop, breakage

EXAMPLE 2 An electrical power utility uses tools, resources, and systems and software to develop complex regulatory filing responses (testimony, discovery interrogatory production of documents, issue summary briefs) for rate case filings and to identify, interpret, and translate highly technical risk issues into executive level summaries for responding to government regulatory filings. Such risk and regulatory project management involves the coordinated efforts of highly-skilled and experienced subject matter experts, along with the use of regulatory processes, protocols, and task tracking matrices.

13 Build and process planning

13.1 General

The purpose of process planning is to assure that build and assembly processes meet the design quality requirements. The charts communicate to all departments involved in production from material supply to shipment of the completed product.

13.2 Quality control (QC) process planning table

The QC process planning table communicates the component design to the production process. It shows the relationship between each component characteristic and the manufacturing or assembly step in the build process. Critical control points are identified to indicate process control concerns.

NOTE The QC process planning table is shown at the bottom of [Figure 1](#). Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this matrix is not included. Readers familiar with the matrix of matrices can recognize this as similar to the G-3 equipment deployment table[23].

EXAMPLE [Table 27](#) identifies key areas in the assembly of the toaster, particularly the installation of the quartz heating element bulb. The process control points include inspecting the bulb for cracks and scratches, cleaning any oil and debris, and proper fit into the bulb power terminals.

Table 27 — QC process planning table for airport breakfast kiosk toaster manufacturing process

No.	Process	Manufacturing and assembly conditions		Component characteristics				Process control points
		Equipment	Index	Glass surface	Cleanliness	Power	Position	
1	Remove bulb	glove		●	●			cracks, scratches
2	Clean bulb	wipe			●			free of oil and debris
3	Orient bulb						●	parallel to terminals
4	Insert left terminal					●	●	spring tension
5	Insert right terminal					●	●	spring tension
6	Place protective cover				●			gaps in cover

13.3 Quality control (QC) tables for component production and assembly

The QC process table describes each of the build process steps in greater detail in order to set operation standards, develop operator training, communicate process specifications, control points, inspection, tolerances, abnormality handling, and other process factors.

NOTE The QC tables for component production and assembly are located at the bottom of Figure 1. Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that these tables are similar to matrix IV. Readers familiar with the matrix of matrices can notice these tables are omitted in the matrix of matrices[23].

EXAMPLE Table 28 details the process for installing the quartz heating element bulb for the airport toaster.

Table 28 — QC table for assembly of airport breakfast kiosk toaster heating element

Product name: bagel toaster		Process: quatrz bulb installation		Approvals:						Control no. QCS1-006		
Part no, QCS1-500B		Issue date: 5/2/97		Plant mgr.	QC	Engineering	Production	Purchasing				
				M Jones	L Ferrara	Stazinowski	A Philips	R Smith				

Process					Control points								
Main process					Control items (check by results)					Sampling method			
Part, mat'l work station	Raw mat'l process	Cost process	Control items	Contents of process	Man, machine, method, material	Degree of importance	Inspection item	Tolerances	Abnormality determined by	Frequency	Sampling method	Measurement method and instrument	Person in charge
Quartz lamps bulk packed in box from inventory				Storage	Method	B	Condition of box		Presence of oil stains on box	100 %	Regular	Visual	Warehouse worker
				Surface wipe remove dirt, oil, foreign matter on bulb	Method	C A	Impregnation Wiping		Control chart	Per 10 boxes	Regular	Visual	Line worker
				Air spray with compressed air to remove all foreign matter	Machine	A	Air pressure	2,5 +/- 0,5 kg/cm²	Control chart	2/d	9:00am 2:00pm	Pressure gage	Line worker

13.4 Process FMEA

Process failure mode and effects analysis is used to identify process problems and improvement. Process FMEA follows the same steps as shown in [9.8](#).

NOTE Process FMEA is included in the cause analysis of problems at the bottom of [Figure 1](#). Readers familiar with the 4-phase QFD model developed by build-to-print auto parts suppliers can notice that this table is omitted. Readers familiar with the matrix of matrices can recognize this as the G-6 table in the matrix of matrices[[23](#)].

EXAMPLE [Table 29](#) shows problems with the reflector substrate injection moulding process. The process engineer has elected to install an automatic injection temperature and pressure controller to reduce misshaping of the moulded substrate.

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Table 29 — Process FMEA table for flashlight with AHP

Failure mode				Failure mode analysis										Action results								
Part name	Function (process/ task)	Potential failure modes	Potential effect(s) of failure	SEV score	Global SEV	Potential cause(s) of failure	OCC score	Global OCC	Current detection method or controls	DET score	Global DET	RPN (sum global SEV+OCC +DET)	Recommend actions	Responsible person and target completion date	Taken actions	SEV score	Global SEV	OCC score	Global OCC	DET score	Global DET	RPN (sum global SEV+OCC +DET)
Relative importance of SEV, OCC, DET																						
Reflector substrate	Support reflective surface	Uneven reflective surface	Uneven light pattern	0.16	0.02	Mis-shapen	0.012258	0.004903	Light pattern test	0.34	0.17	0.19	Control injection temp and pressure	Process engineer, as soon as possible	Automatic controller installed	0.08	0.01	0.000455	0.000182	0.16	0.08	0.09

13.5 Work standards

Based on the quality control (QC) process tables for production and assembly, standard operating procedures and work standards, inspection standards, and check sheets are prepared to assure that manufacturing specifications and tolerances are met, which will, in turn, assure customer satisfaction

with the final product. Work standards should indicate the performance measure, tools to measure, and control method.

13.5.1 QC process table based work standard

This table summarizes critical work measures from the QC process table described in 13.3. It illustrates each process step and critical process point, defines the process control conditions and tool to measure along with the relevant standard, the relevant component quality characteristic, inspection method and documentation, and the reason that the control item is important.

NOTE This table is not shown in Figure 1, the 4-phase QFD, nor the matrix of matrices[23].

EXAMPLE Table 30 describes the injection moulding process for the flashlight reflector substrate. It illustrates the mould and cut points, lists the injection moulder and thermal cutter equipment and operating setting conditions of injection pressure and cutting temperature, the frequency with which these settings be controlled and with what tools such as the pressure gage and thermometer. It includes the component quality characteristics of reflector shape and dimension and their specification values. The quality confirmation and inspection method is detailed for frequency of inspection, the tool such as micrometer, who is responsible for doing the inspection such as the operator, and how they will document the inspection results, such as recording in an x-bar and R chart for statistical process control (SPC). Finally, the reason that this is important is explained as needed for magnification of the light and to improve the reflective power of the flashlight.

Table 30 — QC process table for flashlight

[F] Part critical to function [S] Part critical to safety [R] Part critical to other regulation				Department moulding		Prepared by: TR Date: 3/9/92 Checked by: JR Date: 4/12/92 Approved by: NG Date: 4/14/92		Part no. (internal): 3345AZ3 Part no. (customer): Part name: Reflector						
Process flow	Process point	Process control				Step No.	Process name (equip, mat'l)	Control item (qual char)	Spec. value	Quality confirmation				Reason for control
		Condi-tions	Frequen-cy	Method	Std					Freq	Method	Chk by	Doc	
		Injection moulder				1	Mold sub-strate [F]	Shape dimen-sion	f55 ± 0,1 t = 2 mm	1/lot 1/lot	Microm-eter	Opera-tor	x-R	Magnifica-tion
Mat'l: PVC P/N 54905		Inj. press 30 kg/cm ²	1/h	Gage	IP 62			Finish	zz	1/h	Glossme-ter	QC	Sht A6	Reflective pwr
		Thermal cutter 350 °C	1/h	Thermom-eter	T34	2	Remove flash	No flash	0	All	Visual	Opera-tor	Chk Sht	Ease of assembly

13.5.2 L-matrix based work standard

13.5.2.1 Purpose of the functional requirements-process matrix

This matrix is used to transfer the product functional requirements and characteristics and priorities from the customer needs-functional requirements matrix (house of quality) described in ISO 16355-5 into prioritized process steps and parameters that are related. Control charts for SPC are described in ISO 7870 (all parts)[20].

13.5.2.2 Building the functional requirements-process matrix

The following steps are considered.

- 1) The functional requirements from the customer needs-functional requirements matrix (house of quality) described in ISO 16355-5 are inserted into the rows of the matrix.
- 2) The process steps related to the production of the product are inserted into the columns.
- 3) Using the cause-to-effect approach and working row-by-row, the strength of the relationship of each process step to achieving the product functional requirements and quality characteristics is determined. The icons and symbols described in ISO 16355-5 are used.
- 4) The priorities of the functional requirements are transferred into priorities for processes following the steps described in ISO 16355-5. Optionally, the processes can also be rank-ordered.
- 5) Add process specifications and parameters for critical process steps.

NOTE This table is not shown in [Figure 1](#), the 4-phase QFD, nor the matrix of matrices[23].

EXAMPLE [Table 31](#) shows the importance of each final baking process step to achieving the bagel product characteristics of texture, volume, appearance, and fermentation by-products. Key process steps are baking temperature (360°) and time (6 min). If these are not kept, then all the previous work on developing the best bagel and service will be lost to the customer. From this, [Table 32](#) can be made to give clear instructions to the workers.

Table 31 — L-matrix for bagel characteristics-baking process for airport breakfast kiosk

Baking Process		Priority							
			Storage temperature BP1	Shelf life BP2	Retard thaw time BP3	Proof conditions BP4	Baking temperature BP5	Baking time BP6	
Bagel Characteristics									
BC1	Texture	56,3%							
BC2	Volume	5,1%							
BC3	Appearance	34,2%							
BC4	Fermentation by-products	4,5%							
weighted	Absolute Weight								
	Functional Requirement Weight								
	Functional Requirement Rank								
Specifications			Constant -10°F	max. 26 weeks	33-40°F, 4 hours	unnecessary	350°F in convection oven	6 minutes	
									2,899
									100,0%

Table 32 — Standard operating procedures for airport breakfast kiosk workers

3 Ordering <i># orders/week</i>	1 Order by case if freezer has room, or order daily through commissary. <i>Note all orders in order log.</i> 2 Keep bagels frozen for best shelf life. <i>Any frozen bagels kept longer than 3 d must be discarded. Note in inventory.</i>
5 Display <i>spot count of std met</i>	1 Bagels must be at least 50 % of display case. <i>Set out sufficient display trays for this quantity of bagels.</i> 2 Display at least eight of each variety during breakfast. <i>Whenever there are less than eight, lay the rest flat to create a full appearance.</i>
7 Storage <i>% inventory sold/week</i>	1 Bagels must be at least 50 % of display case. <i>Set out sufficient display trays for this quantity of bagels.</i> 2 Display at least eight of each variety during breakfast. <i>Whenever there are less than eight, lay the rest flat to create a full appearance.</i>

13.6 Other tools and methods

In addition to the above QFD tools, other product development methods are used.

- a) production part approval plan (PPAP)^[4];
- b) design for lean manufacturing^[10];
- c) specific design for six sigma elements^[9];
- d) design for X (DfX) studies, for manufacturability, assembly^[24];
- e) total productive maintenance (TPM)^[8];
- f) world class manufacturing^[7];
- g) flexible manufacturing^[43].

14 Build

14.1 General

Quality checks during full production launch, service start-up, software detailed design, and other activities are made.

14.2 Applicable tools and methods

The following methods are commonly used.

- a) 5S (from Japanese words for workplace improvements meaning sort, straighten, shine, standardize, and sustain)^[31];
- b) poka-yoke (mistake proofing)^[39];
- c) statistical process control^[21];
- d) Kaizen and continual improvement^[19];
- e) design for Six Sigma phase activities, elements and tools^[9];

- f) Six Sigma method to design, measure, analyse, improve, and control (DMAIC) and quality improvement teams linked to design and build plans^[5];
- g) quality improvement storyboards, 7 or 8 discipline charts (7-D, 8-D)^[12].

15 Packaging design, logistics, channel management, consumer information, and operating instructions

15.1 Functional packaging

Packaging engineers are involved at the design phase to better protect customer safety for food, pharmaceutical, medical, and similar products from damage, loss of sterility, insect and debris infiltration, and other damages. Similarly, packaging engineers are involved at the design phase to better protect product integrity from damage and loss of usability during shipping and handling. Packaging engineers are involved with marketing and sales to assure attractiveness, legibility of legal and marketing language, retail-applied labelling, and shelf or point-of-purchase plan-o-gramming. Similar considerations are made to product usage, warnings and cautions, installation and operating instructions, and other information.

EXAMPLE 1 A manufacturer of glass lighting fixtures failed to involve packaging designers early on in the design of a new product shape. Existing packaging materials were used and resulted in 100 % breakage when the product arrived at dealers.

EXAMPLE 2 A beverage company created a new size bottle by increasing its height instead of width. This created a problem for the retailer stockperson, an intermediate customer, who must change all the shelf heights to accommodate the new bottle height.

15.2 Aesthetics and packaging

Packaging design can also affect customer perceptions and emotional quality. Lifestyle deployment described in [Clause 8](#) has been successfully used to help in graphic design for packaging^[15].

EXAMPLE 1 A diet product supplement with a female target segment uses curvy graphics to communicate the benefits to body shape of their product.

EXAMPLE 2 Studies have shown that packaging colour and sound can affect the perception of taste. For example, blue packaging makes food seem to taste saltier, a benefit to older people who tend to add more salt to their food due to declining sense of taste, thus risking higher blood pressure^[42].

15.3 Logistics

Planners are involved with packaging to better protect product during shipping, storage, and handling, particularly for effects of temperature, humidity, expiry dates, and other relevant factors. Other considerations are packaging size to optimize transportation concerns for weight, dimensions, and material handling. Logistics should also consider delivery quantity and availability commitments to customer^[17].

EXAMPLE A manufacturer of electronic devices using a new circuit must secure suppliers of the printed circuit board so that shipping quantities are sufficient for the gift-giving season.

15.4 Marketing claims

When new products add new features and performance levels, marketing, efficacy, safety, and environmental claims are tested and certified for requirements of regulatory agencies involved^[26].

EXAMPLE A cleaning product reformulated for use on human skin must test and provide evidence not only for its anti-microbial efficacy but also for safety over long-term use by seniors, adults, and children.

15.5 Marketing collateral, operating instructions, service and repair documents, service parts

All promotional documentation is updated to reflect new features and functions in the product. Installation and operating instructions are updated prior to product launch. New maintenance and repair instructions, service and replacement parts and consumables, and special tools are made available prior to product launch^[17].

16 Customer support

16.1 General

Customer support (technical, sales, and other field activities) and service (including parts, service training, and other support activities) are made. Information related to design changes, new features, consumables, setup, and other concerns that customers and users could encounter is created. Support databases, support staff, support levels (such as gold, silver, bronze) are created in line with customer expectations and needs. Records of all transactions with customers are kept for an appropriate duration.

EXAMPLE [Table 33](#) identifies several service availability packages for IT services and the appropriate levels of uptime, downtime, outage instances, and so forth. [Table 34](#) describes the technical domain requirements necessary (marked as N) or recommended (marked as R) for the platinum level^[34].

Table 33 — Service availability targets for IT provider

	Platinum	Gold	Silver	Bronze
Service availability (uptime)	99,95 % to 100 %	99,9 % to 99,95 %	99,9 % to 99,95 %	99,9 % to 99,95 %
Total hours uptime per year	8 760			
MTTRS target (unscheduled)	≤15 min	≤30 min	≤4 h	≤8 h
Maximum # of incidents per year (unscheduled)	≤ 12	≤12 ^a	≤24 ^a	≥24 ^b
Scheduled downtime	None	Required	Required	Required
MTTRS means mean time to restore service.				
^a Varies based on actual total hours uptime required. This example assumes 6 570 h/year (18 h/d).				
^b Based on historical data rather than derived from uptime and MTTRS.				