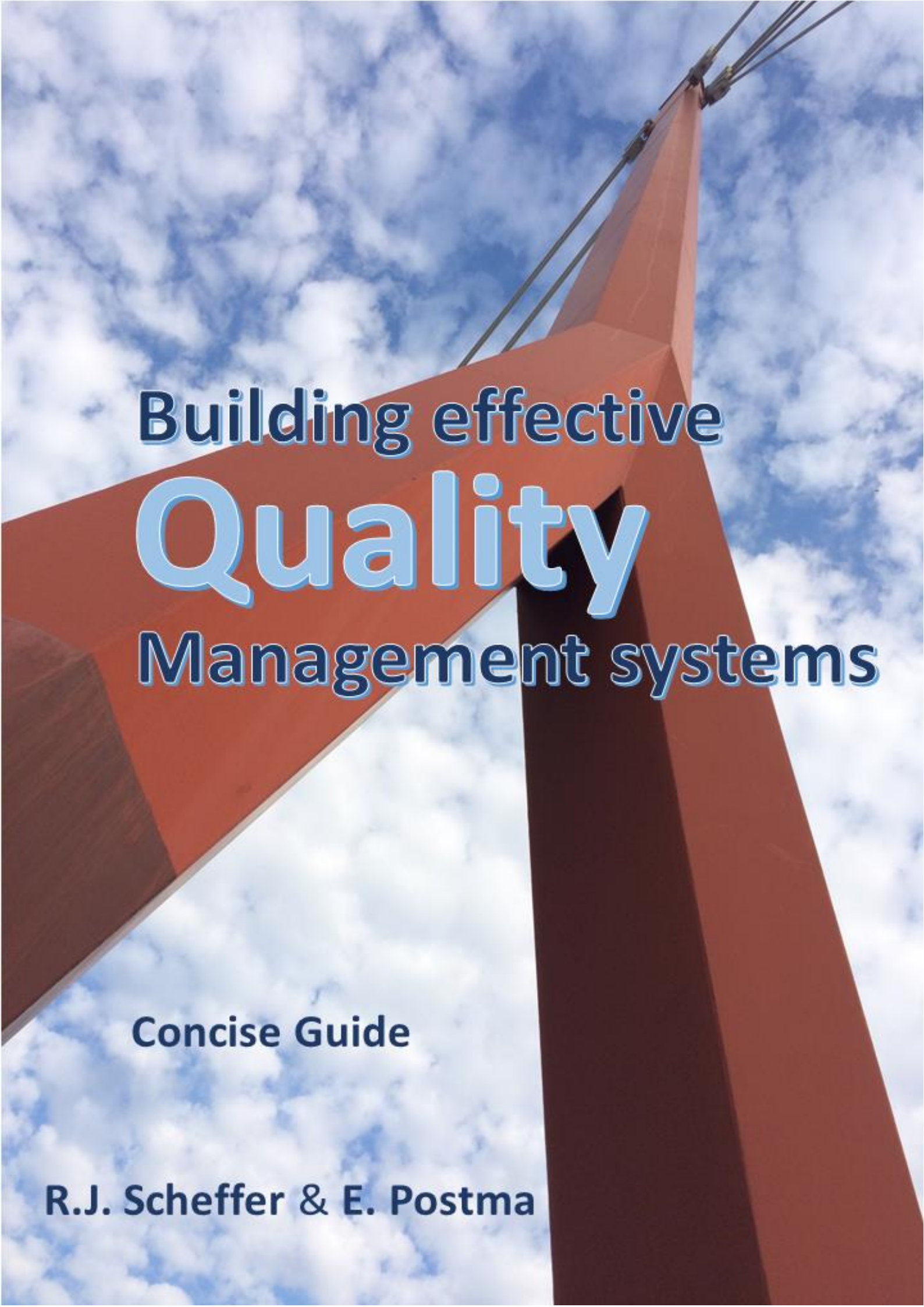

Building effective Quality Management systems

Concise Guide

R.J. Scheffer & E. Postma

Building effective Quality Management Systems – Concise Guide

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Summary

This guide presents a proven, structured approach for building a quality management system that is beneficial to the organizations that implement them. Its focus is on nine core elements, their logical relations within one 'system' and on those aspects where development and implementation of a quality management system may breakdown.

In the ISO 9000 family of standards on quality management core elements of any quality management system have been worked out, like management commitment, focus on processes, customers, competence of persons, and continual improvement. Strengths of especially the ISO 9001:2015 standard *(Quality management systems – Requirements)* are its logical approach, extensive world-wide experience, available expertise, a vast body of literature, the option to be certified by an impartial certifying body, and – most important – it is 'doable'.
Therefore, ISO 9001 is taken as the core of this quality management system structure, with the functions of the organization defined and detailed using the IDEF0 methodology and for further detail (including responsibilities of persons) the *Responsible-Accountable-Supporting-Consulted-Informed* model (RASCI).

Following this guide will lead to a coherent quality management system that supports the organization. Such a quality management system can (and should) become the core of quality management for the organization in its environment, often as part of a chain, with long term leadership and sustainability in its widest sense.

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Preface

When organizations realized that it would be good to know the quality of its products and services, the seed was planted of what has developed into quality management. The path towards quality management started with testing inputs and outputs: quality control. The second step has been structuring processes with proper checks and balances so that quality of the output of such processes was assured. From there, organizations are adopting quality management as an all-embracing philosophy where quality and continual improvement become 'core business'.

In this guide a proven quality management system is presented, developed in collaboration with several industry leading companies. The structure presented is based on experience of what worked in real life and what could be structurally improved.
Following this guide and its proven structured approach assists in building a quality management system – the backbone for quality management – that is beneficial to the organization.

Ruud Scheffer & Erik Postma
March 2019

Why quality management?

It is quite an achievement to build and implement a quality management system based on the ISO 9001 core. It creates clear processes detailed into procedures that define everyone's daily work (and make this transparent to all employees). Besides (internal) clarity such a quality management system will create a structure for continual improvement.

The financial impact of implementing a quality management system has been the subject of several quantitative studies on performance and benefits, with comparable results. It can be expected that after the implementation of a quality management system especially the supply chains gain several percent in efficiency. Better functioning supply chains, fewer complaints and more satisfied customers are proven immediate benefits of well-functioning quality management structures. It is also clear that combining certifications, especially ISO 9001 and ISO 14001, has a synergistic effect. (See the condensed literature review in Annex 1.)

Some background and terminology

The many faces of quality

The word quality is associated with many, sometimes confusing or conflicting, meanings. Colloquial ('This is really a good product"), marketing slogans ("quality brand", "the best quality money can buy") and more precisely defined expressions for which ISO is the authoritative reference.
The question 'What is quality?' therefore has no simple answer. Colloquial it often means good, or perfect. ISO defines quality as meeting agreed specifications, which is not the same as 'good or perfect'. Quality defined as 'meeting agreed specifications' is, in the end, restricted though. Other stakeholders, including those not directly involved, may have additional requirements and expectations, like a small environmental impact, energy-neutrality, and durability. For the sake of clarity, ISO will be followed throughout this guide.

Colloquial expressions like 'good', 'really good' or 'great' are in line with excellence as defined by ISO: exceeding customer expectations; one gets more than expected.

Quality management

A quality management system is a way of defining how an organization can meet the requirements of its customers and other stakeholders affected by its work.

ISO 9001:2015 [1] [2] [3] [*] is a standard that sets out the requirements for a quality management system. It is by far the most widely used standard. Its success is shown by the fact that currently more than a million organizations are certified. ISO 9001 helps businesses and other organizations to be more efficient, improve customer satisfaction and hence improve competitivity; in other words: they become more successful. It is the only standard in the ISO 9000

[*] Literature references, numbers in superscript: see page 26-27.

family organizations can be certified to (although this is not a requirement) and it can be used by any organization, large or small, regardless of its field of activity.
The standard is based on quality management principles that include a strong customer focus, the motivation and involvement of top management, the process approach, employee competency and continual improvement. Using ISO 9001 helps ensure that customers consistently get products and services that meet agreed specifications.

An important further step, beyond ISO 9001, is ISO 9004 [4]. Together with ISO 9001 it provides a unifying basis for an organization's values and strategies. This standard is intended to help organizations to balance the needs and expectations of customers with those of other interested parties and provides guidance to organizations to achieve sustained success in a complex, demanding and ever-changing environment.

Definitions: Quality, QA, QC, QM

Quality
ISO 9000 [3] defines quality as the *degree to which a set of inherent characteristics* (defined as distinguishing features*) fulfils requirements* (defined as need or expectation that is stated, generally implied or obligatory). In other words, for a customer quality means: do I get what I expected, or, does it meet the agreed specifications.

Quality Control and Quality Assurance (QC and QA)
Although QC and QA are often used as if these are interchangeable expressions, they are not. QC is focused on *fulfilling quality requirements* whereas QA focuses on *providing confidence that quality requirements will be fulfilled* (ISO 9000). QC is typically associated with measuring output, like testing products before dispatching them to customers. QA creates confidence by structuring processes, assuring that proper tests and measurements are done, providing work instructions, quality standards, and training of personnel.

Quality Management is defined in ISO 9000 as *coordinated activities to direct and control an organization with regard to quality.*

ISO 9001 and other toolboxes

ISO 9001

The current ISO 9001:2015 standard [2] is based on the idea of continual improvement. It is suitable for organizations of all types, sizes and sectors. ISO 9001 doesn't specify what the objectives relating to "quality" or "meeting customer needs" should be, but requires organizations to define these objectives themselves and continually improve their processes to reach them.

Implementing a quality management system based on the ISO 9001 standard will help to:
- Assess the overall context of an organization to define who is affected by its work and what is being expected. This will enable management to clearly state objectives and identify new opportunities.
- Put customers first, make sure to consistently meet their needs and enhance their satisfaction. This should naturally lead to returning clients and to new clients.

ISO 9001 is a standard that organizations can be certified to: an impartial certifying body can audit the quality management system and if the standard is sufficiently met the organization will receive the ISO 9001 certification. Building and implementing a system based on ISO 9001 does not *require* such a certification. Making this investment in certification has the serious advantage that external auditors will critically review the quality management system and its functioning compared to the ISO 9001 requirements and that this review will be annually repeated.

Other toolboxes

Japanese carmakers are successful and especially Toyota has been studied to understand its success [5] [6]. Toyota has created a culture that places humans at the center of the company. Toyota's success is not to be attributed to only one practice like the **Toyota Production System** (TPS). Toyota does employ several tools that help to continually improve like the 'Plan-Do-Check-Act model (or Deming Circle; Figure 1), the 'ask why five times' routine and its own Toyota Business Practices Process.

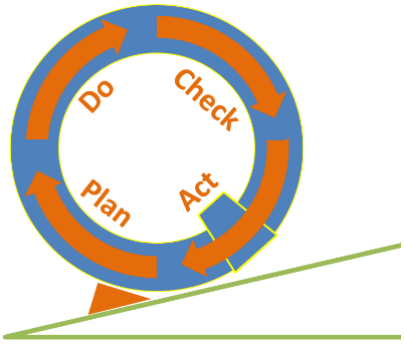


***Figure 1**. The Plan-Do-Check-Act model or Deming Circle*

The general drive in Japanese industry to continually improve has led to '**Kaizen**' with the tag line: *'As no process can ever be declared perfect, there is always room for improvement.'* Typical Kaizen projects are short: a project team works for the full 100% on the topic to improve for up to a week and implementation is immediate.

A rather more complex toolbox is **Six Sigma**. The Six Sigma methodology [7] distinguishes five phases of improvement: *Define, Measure, Analyze, Improve and Control*, together forming one structured problem-solving methodology known by its acronym DMAIC. Improvement projects following DMAIC methodology are usually short (a few months at a maximum) and often use aspects of the Kaizen approach. A major difference is that Kaizen projects typically take a week full-time and DMAIC projects several months part-time. Six Sigma flourishes especially in environments where vast bodies of data are available for analysis. Airports and aircraft manufacturers are examples of organizations able to benefit from Six Sigma efforts.

The **European Foundation for Quality Management** (EFQM® [8]) is a not-for-profit organization, created in 1988 with a mission to be the driving force for sustainable excellence in Europe. EFQM, and national initiatives following the same or a similar approach (like INK in the Netherlands) go beyond the requirements of ISO 9001. EFQM aims for coherence between the organization and its environment; the organization should strive to satisfy all stakeholders now and in the future. The requirements linked to Corporate Social Responsibility emphasize the responsibility for the future: *'Excellent organizations (…) actively promote, social responsibility and ecological sustainability both now and for the future.'* [9] On the current (2018) EFQM website *creating a sustainable future* is listed as one of the eight fundamental concepts of excellence.

Risks and risk analyses

Introducing risk-based thinking in an organization is one of the major changes in the latest version of the ISO 9001 standard [2]. It stresses specifically that top management should plan and implement actions to address risks and opportunities. A positive deviation arising from a risk can provide an opportunity. Many organizations are in a permanent re-active state where non-conformities and corrective actions are launched with the intention that a mistake should not happen again. Nobody likes to make mistakes and correcting mistakes in most organizations is

not perceived as building on an internal culture of improvement. However, thinking in risks and related opportunities provides a great opportunity to engage all personnel, driven by top management, in the philosophy: "think before you do" and assists in building a culture of excellence where mistakes are prevented. Such a culture of excellence changes organizations from a re-active into a pro-active mode, which has a substantial impact on their performance.

Assessing risks, their (potential) impact and how to minimize them has become a key element of ISO 9001, but risk analyses are essential for every quality management system. Up-to-date risk analyses are an essential element of continual improvement.

Of the various, often proprietary, risk tools only FMEA (Failure Mode and Effect Analysis [10]) is discussed here. FMEA has its roots in the aerospace industry in the 1960s and became an effective tool to prevent process and product problems before they occur.
Its core is simple: create a breakdown of all components (of a process or product), identify potential failures, its causes, effects and the controls to prevent and to detect the failures. See Figure 2.
By ranking potential severity of each failure, the expected frequency of occurrence and possibilities to (timely) detect it, the analysis can be prioritized.

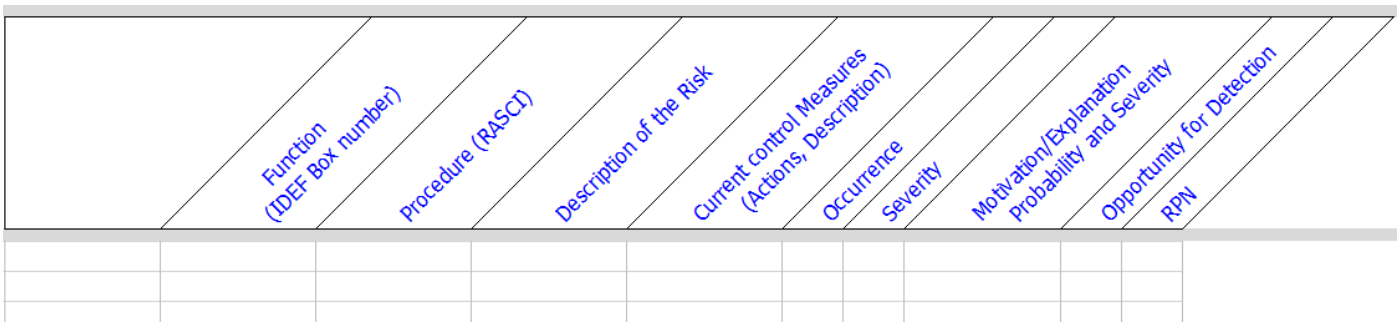


Figure 2*. Typical header fields for a FMEA risk analysis. For the first column, Function (or Process), the IDEF0 box number suffices. The field Motivation/Explanation Probability and Severity isn't mandatory, but it can help to record key points and to reach similar conclusions at a later point in time. RPN = Occurrence x Severity x Detection*

The analysis requires categorizing the frequency of occurrence of the risk, its severity or impact and the possibilities to timely detect the risk. Multiplying these three figures yields the Risk Priority Number (or RPN: Occurrence x Severity x Detection). Many different indexes have been developed. For instance, McDermott *et al.* [10] present scales with 10 categories. A simple and proven approach is with four categories 1 to 4. This leads to something like the following:

Categories of **Occurrence** of Risk or Weakness in the Process Step
1 = unlikely; happens only in unusual circumstances
2 = small, it may happen
3 = average, it will happen every now and then
4 = high, it happens occasionally

Categories of **Severity** of the Damage
1 = very small, no impact on the organization, or small damage
2 = small, influences following activities / process steps, or minor damage
3 = medium, has a negative impact on following activities / process steps, or significant damage
4 = big, continuing is impossible, or big damage

The decision for translating severity into financial categories is to be taken by the organization. For a medium-size organization severity could, for instance, be expressed by its financial consequences as follows. 1: less than € 10,000, 2: between € 10,000 and 100,000, 3: between € 100,000 and € 500,000, 4: over € 500,000.

Opportunity for **Detection** (or detection probability):
1 = the error / issue will certainly be noticed / detected
2 = the probability for detection is reasonable
3 = the probability for detection is small
4 = the probability for detection is (close to) zero

After assigning a number for each risk for Occurrence, Severity and Detection, the Risk Priority Number (**RPN**) can be calculated:
RPN = Occurrence x Severity x Detection

This allows prioritizing within a risk analysis. Obviously the highest RPN figures are to be addressed first. It could lead to, for example, a decision to initiate direct action for each RPN of 16 or above and to prioritize risks and work according to an action plan for the RPNs smaller than 16.
The decision for the cut-off value is to be taken by the organization and needs to be evaluated periodically.

Building and regularly updating risk analyses for all processes with risks – at least for all primary processes of the organization - is an essential element of continual improvement and therefore indispensable for solid quality management.

Why this guide focuses on ISO 9001

The strengths of the ISO 9001:2015 standard *(Quality management systems – Requirements)* are its logical approach, extensive world-wide experience, available expertise, a vast body of literature, the option to be certified by an impartial certifying body, and – most important – it is 'doable'.
In this guide, therefore, ISO 9001 is taken as the core of the quality management system structure, with the functions of the organization defined and detailed using the IDEF0 methodology and for further detail (including responsibilities of persons) the *Responsible-Accountable-Supporting-Consulted-Informed* model (RASCI).

The Toyota Production System, Kaizen efforts and Six Sigma projects focus on improvement. They are examples of toolboxes that benefit from a well-functioning quality management system. EFQM has a wider scope, including social responsibility and ecological sustainability, which makes a meaningful implementation more difficult. *Start with ISO 9001* would be our advice. Up-to-date risk analyses of key processes are critical for the continual improvement efforts of any ISO 9001 implementation; the paragraph on risks and risk analyses is meant to assist in creating and maintain such risk analyses.

Building a Quality Management System

This guide provides one consistent approach, describing what an organization does (its functions), and, when entering a more detailed level, who does it.
For the functions of the organization (the 'what') the function-modeling approach known as IDEF0 will be used. The IDEF0 models fit seamlessly to responsibility matrices (based on the so-called RASCI model) that describe the 'who'.
IDEF0 models, further detailed in RASCI-based procedures, meet the process approach requirements of ISO 9001:2015 and greatly facilitate measuring process performance.

Enterprise, Process and Function Mapping

Many models have been developed to describe enterprises and organizations, for many different purposes and in very different detail levels.
We have chosen to use the function-modeling approach known as IDEF0 to describe the functions of the organization (the 'what') because of its flexibility and, although beyond the scope of this guide, because IDEF0 is a very good tool for business reengineering.

Functions and processes are not departments. Function-oriented models define the types of activities irrespective of time, whereas process-oriented models show sequences of activities. Therefore, a function model has one single activity box for a specific type of activity.
Often several departments are responsible for a set of related activities that would be grouped into one function-oriented model. Similarly, one process often belongs to more than one department. Therefore, when describing an organization, care must be taken not to describe the different existing departments. Weaknesses, conflicts of interest, responsibility issues and options for improvement become clear when an organization is described from other viewpoints, like how a product moves, how information flows and so forth.

Process and function mapping is about functions that execute tasks and duties as described; however, behind these maps are real employees who perform the actions. ISO 9001:2015 has been a big step forward over its previous version in making organizations understand that it is essential to understand the competency of their staff. Information as such is not sufficient anymore to provide proof that the Quality Management System is functioning. Employees need to be trained to understand the context of their work and the deployed processes. In other words, each employee needs to understand the relevance (or for commercial organizations the added value) of his or her work. Only when the consequences of individual actions in the larger framework of processes are well understood optimizing the process as a whole can be effective.

Besides the IDEF0 method and RASCI tools, detailed below, many process mapping tools and methods are used. Main examples are:

- Flow charts, describing the flow of information, products or goods with decision points.
- SIPOC diagrams (SIPOC = suppliers, inputs, process, outputs, customers); a typical six sigma tool to describe processes and stakeholders.
- Process observation (lists with detailed steps of processes, often with timing and distances between steps; used in factory processes. Helpful for "lean" projects and six sigma analysis).
- Transportation and spaghetti diagrams (follow-up of process observations; depict the physical flow of work or material in a process).
- Swim lane flowcharts (shows interactions between departments).
- Value stream maps (capture details of each step like setup time, processing time, waiting/queuing time, info on complexity of the step, …).

These are *all* focused on following the process: one can follow the flow of information and/or the flow of the product through the process. All have their own values and weaknesses and especially when redesigning a process or when working on improvements of a process one or more of these tools can be helpful. However, none of them provides a clear view on the entire organization, whereas simplicity of a completed IDEF0 model is a compelling strength of the IDEF0 method over other methods and tools: IDEF0 charts provide an overview in one glance, which facilitates understanding the organization and the relevance of each of the described steps.

IDEF0 basics

IDEF0 ('IDEF-zero' or IDEFØ using the mathematician's Ø to distinguish a zero from the capital O) is a method for system analysis [11]. It has its roots in the US Air Force in the early 1980s. IDEF0 was designed for function analysis and can be used to create a function model of an enterprise; other IDEF toolboxes have other purposes, like data analysis and building an information model for IDEF1.

The expression IDEF0 is best be used as a name as several explanations for its acronym history are used, like *Integration Definition for Function Modeling (IDEF0),* being the title of the Federal Information Processing Standards Publication 183 (1993) [12], *Integration DEFinition for Function,* and *Icam DEFinition for Function Modeling*, where 'ICAM' is an acronym for Integrated Computer Aided Manufacturing.

The strength of IDEF0 is that it leads to clear graphical representations of systems, organizations, factories and the like. IDEF0 is flexible and allows different viewpoints. Its flexibility makes it a suitable tool for business reengineering.

The IDEF0 function modelling approach is exceptionally well suited for business process modelling: to describe what an organization does to meet the expectations of its stakeholders. For commercial enterprises sustainability and remaining competitive are critical stakeholder requirements, for not-for-profit organizations these are sustainability combined with enhancing efficacy and efficiency.
Within organizations processes and associated activities (functions) form a structure that describes the purpose of the organization: serving its clients and meeting the requirements of its stakeholders. The strength of using the IDEF0 function mapping approach is that it clearly identifies distinct activities (functions) that have a specific purpose in the functioning of the whole. For each activity there is a single IDEF0 activity box that describes the activity by a verb phrase: e.g. perform packaging or check quality.
The huge added value of the IDEF0 function mapping lies in the fact that on the activity box the top is used for showing constraints: elements that need to be considered when executing the activity. These can be safety rules, quality requirements, or for instance legal constraints. Furthermore, the bottom is used to transparently show what is specifically needed to perform the activity, like software, machines, employee resources or a support activity depicted by another IDEF function box.
The activity boxes are linked by arrows that show their interaction to complete a process. Most processes are completed by the execution of activities in several IDEF0 boxes where one activity either is the input, or it supports the action performed in another activity box (an arrow either is an output in one box and an input in another one, or the output arrow enters the bottom of another box.) A constraint is clearly visible as a constraint because the arrow enters in the top of the activity box. The completed IDEF0 chart clearly shows the added value of activities to the total process that leads to a service or a product: the activities and their relations that create the service or product, plus the support and constraint activities that are essential for the total process to function.

Six key points of IDEF0

- IDEF0 can be used for any system.
- IDEF0 is not a flow chart – it does not prescribe a sequence of operation.
- IDEF0 is a constraint model as it displays all constraints on each function.
- Each function box on an IDEF0 chart depicts the function described by the verb phrase written in the box. The arrows depict things that are needed or produced by the function.
- IDEF0 describes what a system does – its function. Not how it does it.
- IDEF0 is a tool that supports business process reengineering.

IDEF0 function mapping

To map the functions of an organization, firstly the purpose must be defined, and a viewpoint chosen as this controls what is included or excluded.

The **purpose** of the IDEF0 model defines why the model is developed. It is sometimes included in the top-level chart of the model, node A-0 (see Figure 4).

The **viewpoint** is the perspective of the model. The perspective is one of many possibilities, like materials/goods/products, or financial, or management, or information, or human resources, or any other viewpoint that is required for the model's purpose. IDEF charts should not show data from different viewpoints of a system as this typically makes the charts (too) complex.
In the following (esp. the Figures 4 to 6) the viewpoint chosen is information needed to reach customer satisfaction by delivering a product and/or a service.

When building the model, the basic question is what distinct activity boxes are needed to build a complete IDEF0 model within the chosen purpose and viewpoint.
Although in most organizations activities are organized in hierarchical structures like departments, IDEF0 models do not show these structures when the viewpoint is not management. It can help to understand the current hierarchical structure by creating IDEF0 charts ('as is' situation) with a management viewpoint and the purpose to review the management structure.
Relevant questions for each IDEF chart created are always: 'What is the relevance of each individual activity box or the added value to the total organization?', and 'What would happen if this box would not exist?' This touches an aspect of the IDEF0 toolbox not highlighted here: its use for business process reengineering [11].

Using the information viewpoint (information needed to reach customer satisfaction by delivering a product and/or a service), the top-level chart of the model, node A-0 (see Figure 4) shows client demands as input and as output satisfied clients as well as content shareholders. The strategy deployed determines success; it is a constraint because all the organization should be aligned around the strategy and not waste time and resources on activities that are not in line with it. Figure 6 provides the next level IDEF0 chart, node A0, with the same viewpoint perspective. As purpose and perspective were defined when starting to build the IDEF0 model, these obviously do not change within one model (but developing more than one model may be useful).

Practical aspects and conventions of IDEF0

Building a set of IDEF0 charts is not particularly complex, but it does require consistency and carefully adhering to the IDEF0 conventions. In the following figures (Figure 3 - 6) some basics of IDEF0 boxes, charts and their hierarchy are outlined.

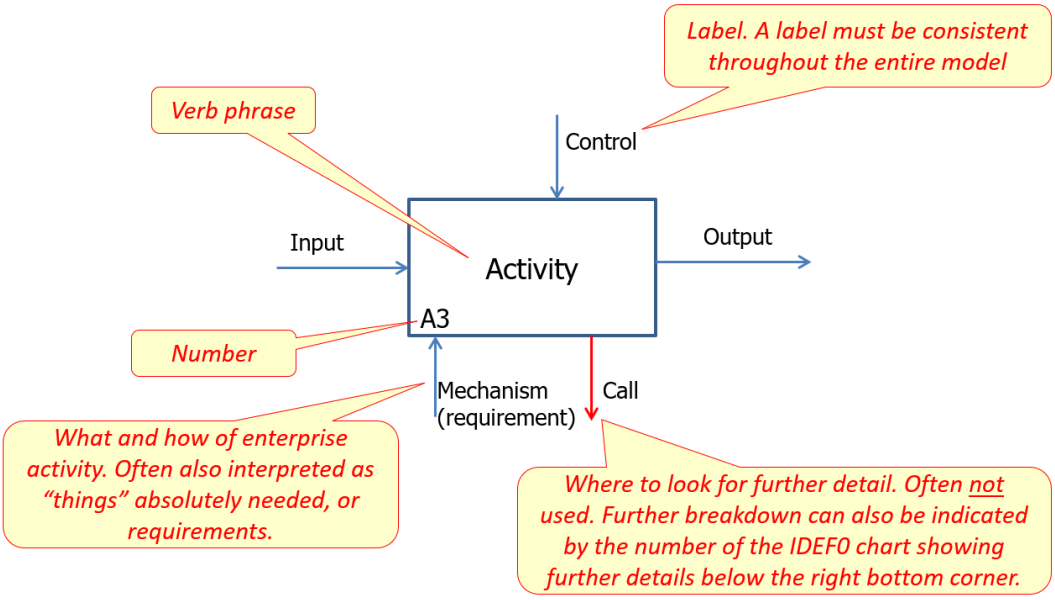


***Figure 3**. Structure of an IDEF0 box. The activity in the box is described as a verb phrase (*'what does it do?' *- never a department). Usually the box has one or more inputs and outputs. The labels of all arrows are to be consistent throughout all IDEF0 charts.*

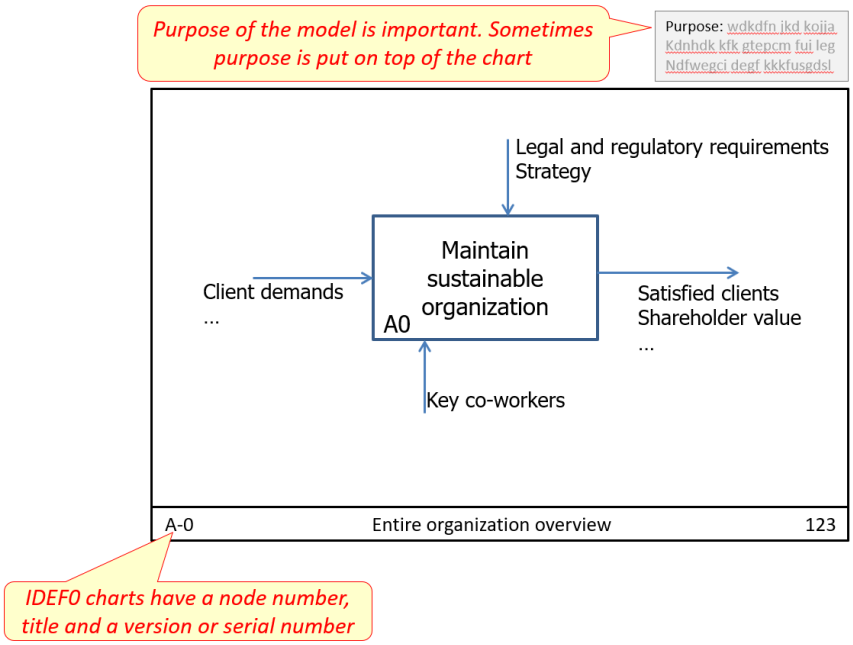


***Figure 4**. A complete IDEF0 chart of an entire organization (enterprise, company, not-for-profit organization). The activity at this top level is being and remaining a sustainable organization, with client demands as input (and probably other inputs as well) and happy clients and share-holders as outputs. (There may be more outputs.) Key constraints are legal and regulatory requirements and the strategy of the organization. Without its co-workers the outputs cannot be achieved.*

IDEF0 node numbers

The top level IDEF0 chart is coded A-0 (A minus zero; this is the node number of the chart). It describes the entire organization in one box, coded A0 (A zero). See Figure 4.

The next level chart has node number A0. It is the highest-level breakdown of the organization in its main functions. The boxes depicting these are coded A1, A2, A3 and so forth. See figure 5. If relevant, one or more of the boxes A1, A2, (…) can be further detailed in next level IDEF0 charts.
If box A3 is further detailed the next level chart has node number A3. The boxes in chart A3 are coded A31, A32, A33, and so forth. Similarly, if box A4 needs further detailing, the next level chart has node number A4 and the boxes in the chart are coded A41, A42 and so forth.

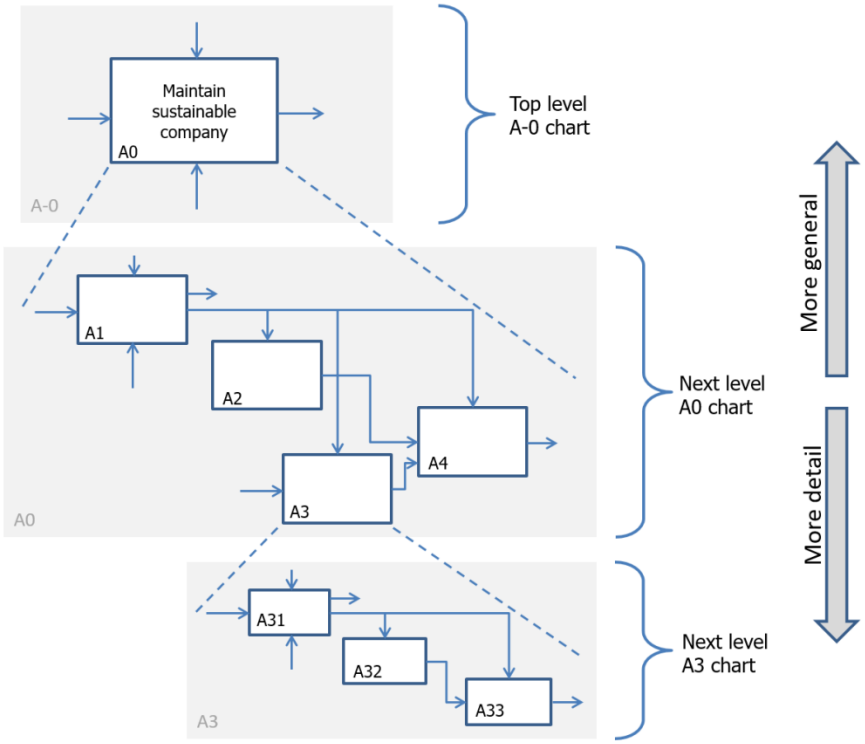


***Figure 5**. Hierarchy of IDEF0 charts. Note that for the lowest level shown (box A3 decomposed in chart A3 with boxes A31, A32 and A33) similar further detailing could be relevant for other boxes (A1, A2, A4). Also, it may be that further detailing is needed for boxes in the A3 chart, leading to an A31, A32 or A33 chart.*
When building a hierarchical set of IDEF0 charts, at some moment further detailing will not add to satisfy the purpose of the model. Often the resulting charts would be too simple: the output of the first box is the input for the second box, the output of the second one the input of the third, and so forth. Instead of this IDEF0 chart a RASCI-based procedure should be written.

IDEF0 do's and don'ts

The strength of the IDEF0 model is its simplicity. Therefore: follow the rules.

Main don'ts are:

- Avoid that charts become too complex. Six boxes in a chart is the maximum. Calculate the 'fog factor': the sum of all boxes + all arrows + all arrow crossings + all arrow forks or joints should be <50.
- Be careful to maintain viewpoint focus. Charts should not show many kinds of data from different viewpoints of a system. (Viewpoint can be product, management, financial, technical, …)

IDEF0 validation

A first step in model validation is to check consistency of all boxes & arrows. Decomposing a few boxes helps to ensure that the model is correct.

The author(s) should find readers for the next step. A continual cycle author/reader is preferred; an alternative is a 'walkthrough session' with a group of readers (typically persons directly involved in the functions described in the model).

Basic questions for readers are:

- What controls each activity?
- How does an activity respond to erroneous arrow content?
- Is there feedback to previously completed activities?
- Which inputs and controls are used to produce each possible output?
- Which events trigger activation of the IDEF0 chart?

Further questions can be many, depending on purpose and goal of the chart. The result is a consistent set of IDEF0 charts that constitute a function model of the organization with a consistent viewpoint. (In some cases, more than one model, with different viewpoints, can be required.)

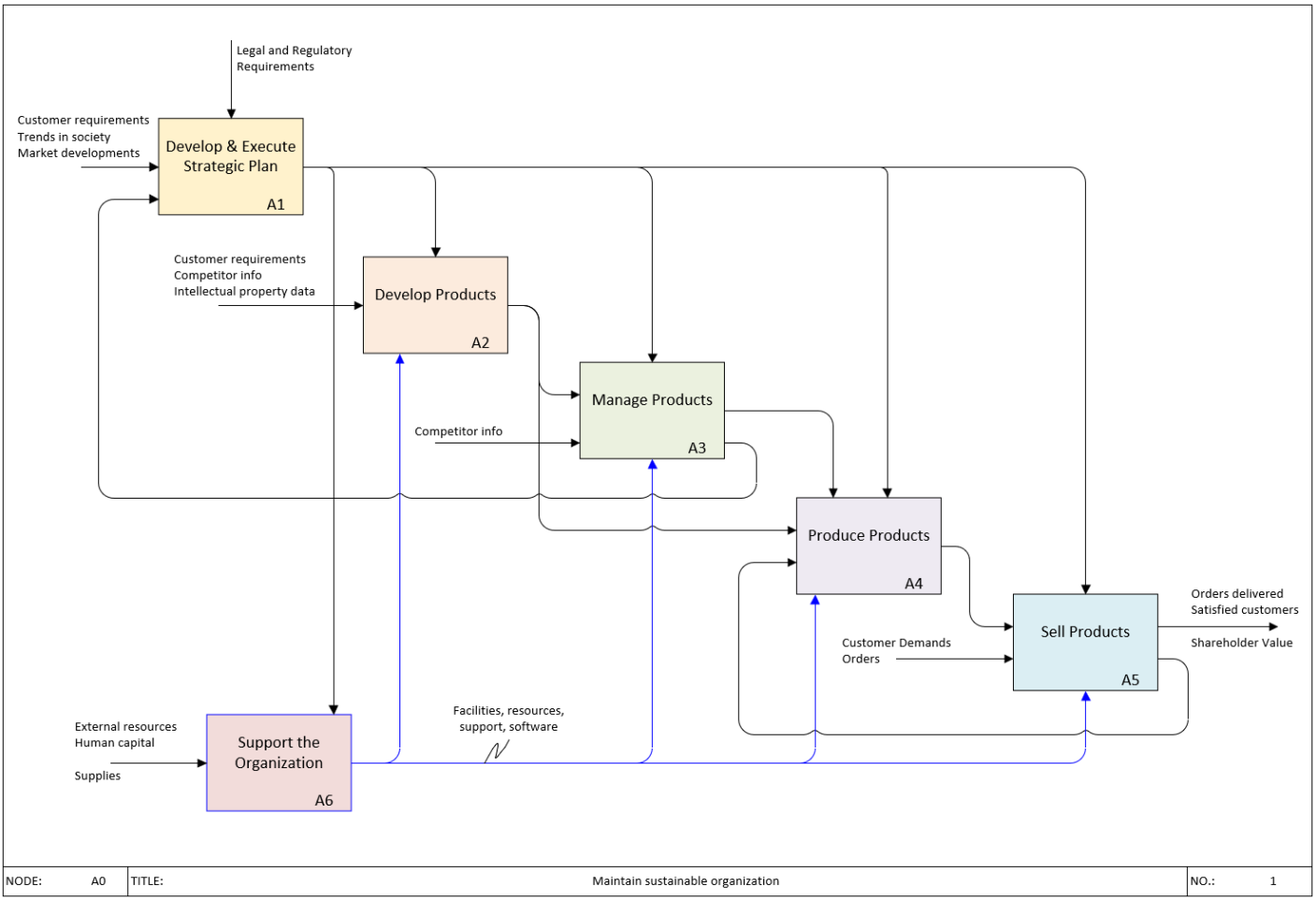


Figure 6. *Example of a full IDEF0 chart, node number A0 (the highest-level breakdown of the organization in its main functions) of an equipment production company. See also figure 8 for one of the RASCI-based procedures belonging to box A4.*

RASCI and other models

Clarity is required on tasks, responsibilities and accountabilities, delegation (what can be delegated to who), boundaries (where stops one responsibility and begins another), and communication.

The IDEF0 function model can effectively describe the main and support structures of the organization. When building the model, it will become clear at a certain moment that further detailing in the form of IDEF0 charts isn't relevant. Not being relevant means in this context that a further detailing would go beyond the description of one specific business task or duty. Arriving at this level will create automatically the demand for the next phase: who in the organization execute the tasks and duties that are described in a coherent IDEF0 map structure.

An elegant way to link the "who does the actions" to such detailed processes is to create the required clarity on responsibilities is the so-called RASCI model. This model distinguishes five roles: Responsible, Accountable, Supporting, Consulted, Informed.

RASCI's do not describe persons – *so, not Mrs Green or Mr. DeWitt* – but roles and duties that are grouped by the organization in job profiles. These describe the jobs were people apply to when they want to join an organization; roles are subtler. A shop floor planner may also have the role of, for instance, production data analyst or the purchaser for tools used in the factory, especially if these roles are asking a few hours per week that do not allow hiring persons for those activities. So, a person with a specific job may have more roles.

Creation of RASCI's linked to the processes of an organization allows management also to look at which tasks and duties should be logically combined into one job profile. As an example, an organization should avoid creating a position that has essential tasks and duties in more than one process. This because in that case the employees in these positions will have difficulties supporting the efficient execution of both processes in parallel: they wear multiple hats.

An alternative to the RASCI model is the DACI model, with different roles. Where the RASCI model has: Responsible, Accountable, Supporting, Consulted, Informed, the DACI model knows: Driver, Approver, Contributor, and Informed.

If an employee is responsible for growing plants, for assembling a product, for managing an assortment and so forth, it is the job of that person to do that work well. He or she is responsible for that work. If someone manages a department or company, he or she again is *responsible* for that work. In the RASCI model: an 'R'. That does not mean that this person must do all the work associated to the task; support may be needed, or others may have to be consulted: the 'S' and 'C' in the RASCI model.

In the DACI model it appears like the employee is the C (contributor), but that someone else is responsible.

The RASCI model is in line with 'empowering people': *If you are hired for a job you are responsible.* The DACI model suggests that people work for an approver: they do what the boss likes. A rather outdated business model, and not effective.

RASCIs can be presented in a simple responsibility matrix like below (Figure 7), but in practical use the matrix is used as the core of a procedure that describes a simple process with all persons (actually roles) involved, its place in the bigger picture of the organization, requirements and measurements.

Input 1	⇨	Action/process step 1	RASCI for step 1	⇨	Output 1
Input 2 (often output 1)	⇨	Action/process step 2	RASCI for step 2	⇨	Output 2
(Etc.)	⇨			⇨	

***Figure 7**. The RASCI logic. Subsequent process steps or actions have an input and an output. The role responsible for the action is shown, if relevant also those supporting, consulted and informed.*

A procedure, with the RASCI structure as its basis, describing a made-to-order product that needs to be assembled could look like Figure 8.

Creative Equipment Manufacturing Company
belongs to: Produce in-house, A4

Custom-made production
Procedure PR 105, version 3

owner: Manager Production

Control frames	Requirements	Performance-indicators
Quality specifications custom-made orders	ERP software	On-time delivery
Capacity		

Input		Process step / action	Manager Production	warehouse employee	shop floor planner	production expert	production assistant	QC specialist	Leader Logistics	Output
		R = Responsible A = Accountable S = Support C = Consulted I = Informed								
		Procedure accountable	**A**							
ordered parts received	1	check and update ERP software		**R**						ordered parts in stock
ordered parts and parts reserved	2	collect and transport all parts to plant		**R**	**I**					Parts in plant
Parts available	3	Plan production, update ERP software			**R**	**C**		**I**		production planned
Parts available	4	Assemble client order to specifications				**R**	**S**			Equipment assembled ready for testing
Equipment ready for testing	5	Execute agreed tests			**I**	**I**	**S**	**R**		Issue quality certificate if tests are passed. If failed: goto procedure *Handling Production Nonconformities*
Equipment + certificate	6	Transport to logistics department			**I**		**R**		**C**	

***Figure 8**. Example of a full procedure based on the RASCI structure. It is assumed that 'sales' has accepted the order for a custom-made piece of equipment and that parts not in stock have been ordered. This procedure describes the production till the equipment is ready for shipping. See also Figure 6 for the IDEF0 chart to which this procedure belongs as one of the procedures linked to box A4.*

A complete procedure as presented in Figure 8 clearly has the 'RASCI' as its central part.
The procedure has only one accountable (**A**): the role ultimately responsible for the process described in the procedure. Often this is the manager of the hierarchically highest-ranking role in the matrix. The other roles are:
R = Responsible: those who do the work or are responsible that it is done. There is only one responsible per task or action (one row in the matrix).
Note that often the 'R' is responsible that a task or action is carried out, whilst the work is delegated to the 'S'. There can be more than one support role per task / action (a line in the matrix).
S = Support: assists in completing the task / action.
C = Consulted: those which opinions must be sought. Two-way communication.
I = Informed: those who are kept up-to-date or informed about completion of the task / action. One-way communication.

Besides the general header (often generated by the software used), the procedure has fields for control frames, requirements and performance indicators. Control frames typically define boundaries for the process described, like legal requirements and restrictions, budget, specifications to be met, and so forth. Requirements are, like in the IDEF0 charts, absolute necessities. Performance indicators allow measuring how well the process functions; they are important tools for continual improvement. A procedure should have at least one performance indicator.

Model hierarchy

Structures visualized as IDEF0 charts describe the 'what' - organization-wide.
Procedures summarize responsibilities and describe the 'who' – organization-wide.

The model hierarchy dictates that essential actions, performed within an IDEF0 activity box, are logically executed by employees who have a specific role. Hence each IDEF0 activity box should have a procedure with a RASCI matrix attached to it. Of course, there can be more than one procedure attached to an IDEF box.
Both the set of IDEF0 charts and the associated procedures with their RASCI matrices are required!

Work instructions list activities in sufficient detail: the 'how'. They can be local (if the organization has multiple locations…) Work instructions are only made if needed. See also Figure 9.

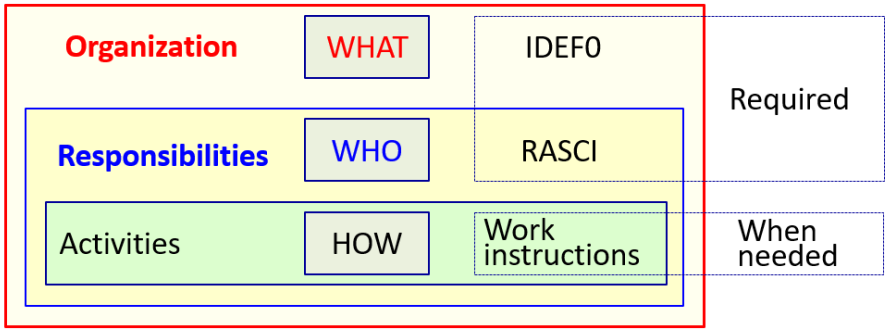


Figure 9. *Schematic representation of the model hierarchy with the three levels: what an organization does, who does the work and how is the work done.*

The benefit of combining the IDEF0 modeling and procedures based on the RASCI matrix as an integrated model is further explained in Figure 10, an overlay between an individual IDEF0 box, its input, the action performed in the IDEF0 box, its result, plus the constraint or control and the requirements (resources needed to perform the action). In the associated RASCI matrix all the elements of the IDEF0 are transparently visible. The RASCI adds only the following essential new elements.

1. The action of the IDEF box is detailed to the extent that each line only contains one role responsible for the execution of the action written in the line.
2. The RASCI line contains all others collaborating to perform the action.
3. To monitor that the procedure is under control, it should contain at least one performance indicator that allows showing that the procedure is controlled.

As such it creates total transparency between the WHAT and the WHO. The RASCI matrix can be further extended by adding the HOW between the input and the action in the RASCI matrix. Work instructions are only needed when the task which is described in the line can be differently performed, resulting in a variable output, dependent on the actual combination of persons associated to each of the roles in the line. If education, training and competency assure that the action is clear for all roles involved, then a work instruction should not be made. However, when there is a risk that different persons could execute the action so differently that the output becomes variable, a work instruction is required.

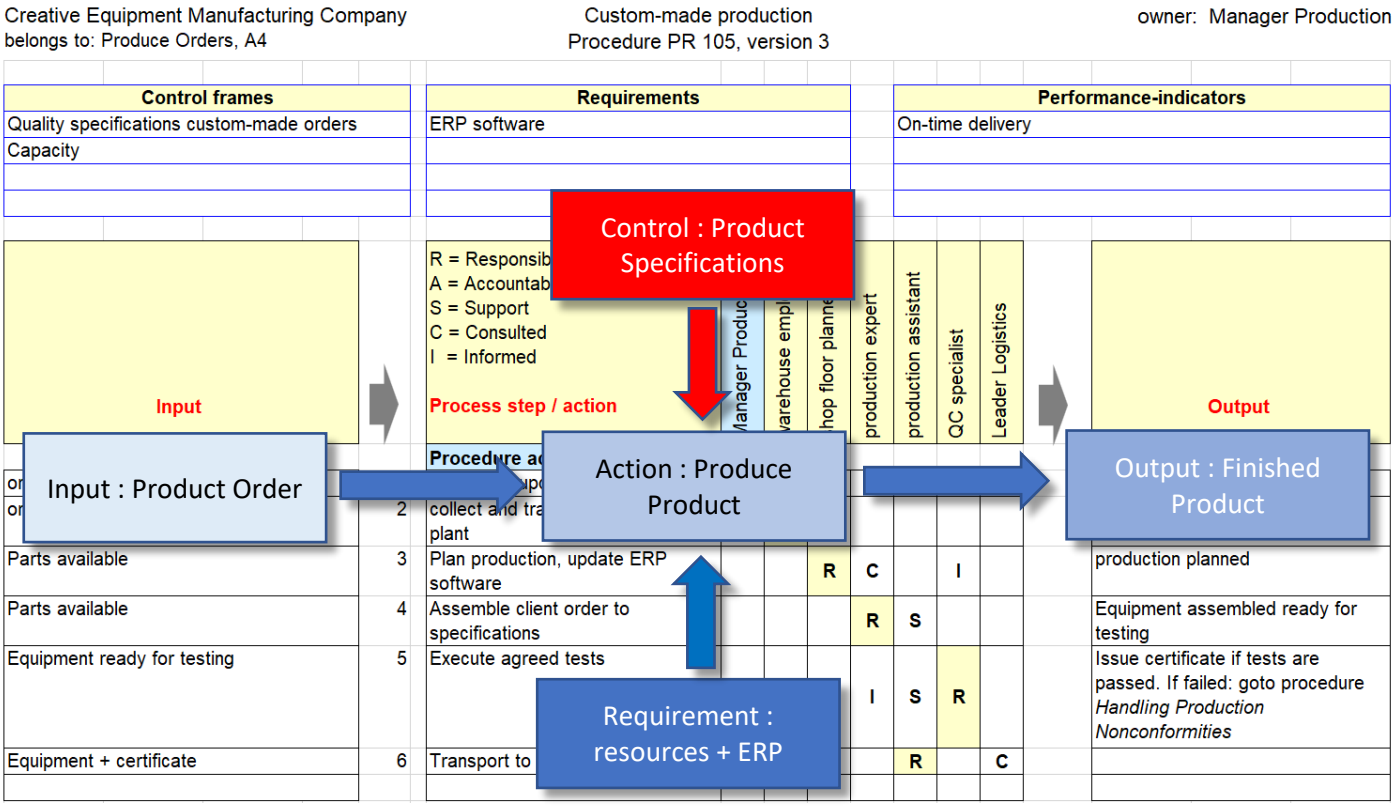


Figure 10. *Schematic representation of the model hierarchy with the relevant 'core' of the IDEF0 chart (Figure 6) as an overlay over a RASCI-based procedure linked to that IDEF0 chart (Figure 8). The IDEF is at a higher level, less detailed, but has the logic: input, output, and the effort to transform the input into the output. Product specifications control the effort in the central IDEF box; key requirements are resources and the ERP software.*

Normal operations and special efforts: projects

There is logic in distinguishing the normal operations of an organization from special efforts that can be handled as projects. Normal operations are: providing the products or services that meet customers' expectations.
Projects should not be part of the normal operations, have a clear goal and are always time-bound. In other words: projects are to achieve something by a specific date, usually with a defined budget and resources.

A wealth of literature exists on projects and project management, but since its release in 1996 the PRINCE2 ('PRojects IN Controlled Environments') [13] [14] model has become by far the most commonly used project management tool. In the PRINCE2 model the project manager is responsible for the entire project as described in sufficient detail in a document known as Project Initiation Document (PID).
The PID is in PRINCE2 documentation described as the 'contract' between the project manager and the Project Board.
The Project Board has to provide resources and will be consulted if the project is on a course that will lead to exceeding agreed 'boundaries' (time, budget, deliverables/results and so forth)

described in the PID. In the PRINCE2 model projects are well separated from normal operations, with a project manager and not line management being responsible for a project.

In the above-mentioned DACI model the driver role is like a project manager. The approver either approves or refuses approval for decisions affecting progress of the work being done by the project team or work group. In the DACI model the project manager clearly is the 'D', but there is also an actively involved 'A'. That is inconsistent with the logic of the Prince2 project management model. The project manager should be responsible and does not need further approvals. In the RASCI model this conflict doesn't exist: the project manager is responsible, the 'R'.

Projects that do achieve their goals by the agreed date without exceeding budget and planned resources are successful, but the project results are often only partly captured because they do not become part of the structures of the organization. If the results are not embedded in the IDEF0 charts and the associated procedures it is likely that they do not become part of the 'collective knowledge' and ways of working. Therefore, adapting IDEF0 charts, procedures and if relevant work instructions, as well as adequate training, should belong to the implementation phase of a project.

The nine main steps towards a good quality management system

Developing and implementing a quality management system requires more than describing functions, responsibilities, probably some work instructions and one or more improvement tools. Below we describe the nine main steps to be taken for successfully implementing a quality management system. All nine are critical; none can be omitted.

1. Create commitment

Before initiating a project to build and implement a quality management system, clear commitment is required of top management and, if relevant, owners or financing stakeholders. This commitment must be clear and visible in the organization. Quality management initiatives fail if commitment of the top is doubtful or if involvement of the top is absent or limited. This is the main threat for the successful implementation and use of a consistent quality management system in an organization.
Crosby [15] [16] (the creator of the maturity matrix) hammered on this issue: *"Unfortunately many leaders are led to thinking that installing a QA system takes care of quality management. This is like thinking that possessing a driver's license produces a safe driver."* He also emphasized the quality management is a philosophy and that quality is management's job.

2. Describe the main & support functions (processes)

Many tools exist, the choice can be based on experience and specific needs. The IDEF0 model is not utterly complex, links very well to further detailing using responsibility matrices like 'RASCI' and can be used for process re-engineering.

3. Define responsibilities

Functions defined in step 2 above typically need further detailing to create the direct link to people's work. Per process step an input, the action or process step(s), responsibilities for that

action or process step and the output should be defined. Procedures based on the RASCI model fit seamlessly to IDEF0 main function charts.

4. Ascertain consensus on processes/functions, responsibilities and further documentation

Describing the main functions of the organization will have gone through an extensive validation process. Further detailing processes into steps with the persons involved could only be done with the active participation of persons representing all roles described. Typically, some, mainly minor, changes from the existing ways of working and of existing responsibilities are now in the new documentation. This needs to be discussed with all involved, including management and if relevant personnel or human resource staff.

If major changes have been identified in steps 2 and 3 above, leading to significantly different main functions and processes and probably restructuring existing structures in the organization, these changes should not be part of the project to implement a quality management system. Process reengineering (using the terminology of Feldmann [11]) needs a separate project.

Upon completion of these steps towards a good quality management system above, it is time to define what more documentation is needed. There may be one or more policies defining internal rules to be adhered to by everyone, a strategic plan outlining a multi-year path forward, product specifications to be met, work instructions for efforts that do need a detailed description of all steps to be taken and forms – empty templates to be filled with data. These documents complete the quality documentation needed (and required for an ISO 9001 certification).

5. Implement suitable software

Quality management needs documentation and the bigger the organization is, the more critical it becomes that such documentation can be easily accessed. Therefore, a parallel effort to step 2 and further should be an evaluation of software tools that would support quality management. The question to be answered is: would a simple tool suffice, or is dedicated quality management software worth the investment?
A digital document retrieval system may be all that is needed. Such a tool should guarantee that every user accessing a document is certain that this is the valid version. Something must be in place to allow for proposals for modifications / improvements of existing documents and such proposals should follow a defined work stream to be evaluated and decided upon.
More ambitious is to adopt software that can do more. A document system (a 'digital binder') is relevant but has limited value in supporting the organization to meet requirements of customers, society or authorities, or to improve.
Software that allows to track all aspects of Quality Management exists and does more to support the organization. A document and content software platform that works in concert with risk management allows linking risk and opportunity analysis to published processes, procedures and work instructions. This facilitates reducing risks and capturing opportunities. A further integration with the registration of trainings & competencies allows management to actively monitor staff competency. Management of continual improvement integrated into the above allows for managing improvement projects and the implementation of related changes in documents and trainings to capture the results. Audit planning, registration of non-conformities and the execution of corrective actions provides a further integration and support to management. Reporting of (key) performance indicators can show progress and supports periodical management reviews of the functioning of the quality management system. Finally, a transparent registration of compliance to safety, health and environmental requirements can be added for monitoring and to show the importance of all staff as being the most important asset, by this

extending the scope of the Quality Management system to the role of the organization in the society at large.

6. Embed quality management in the line organization

Quality management can only be successful if it is embraced by the entire organization. Sufficient resources are needed to support line management as well as all other employees with quality management related efforts. Most effective is to appoint persons within each department who fulfil this role (basically a part-time job next to other duties). These people need to be properly trained and to become members in a quality management network within the organization. The network serves as a platform for exchanging best practices, and as a peer-to-peer network for exchanging information, answering questions and assisting in additional trainings.
The (central) quality management group, unit, or department, can be instrumental by supporting members of the quality management network, providing trainings, measuring output, organizing meetings and audits, communicating successes, monitoring the functioning of the entire quality management system and being the permanent link to top management.

The pitfall of delegating quality management to the quality management department

Building and maintenance of documentation, auditing and the follow-up, continual improvement actions and projects seemingly can be fully delegated to a (centralized) quality department at middle management level that should reach out to other departments. This approach, without visible commitment *and* involvement of top and middle management, will not bring the benefits of a well-functioning quality management system.
When quality management is (formally or in practice) owned by the quality management department instead of being embedded in all departments, a disconnect will develop between the actual work in those departments and the description of those efforts by the quality management department staff, as these persons are not the experts on the work. The resulting lack of ownership leads in the end to quality documentation that is hard to maintain because of limited enthusiasm in the organization, that audits are hard to organize – everyone is too busy – and that the beneficial aspects of quality management: continual improvement and customer focus, are not maturing.

Maturity Matrixes

Maturity is often defined as the extent to which a process is explicitly defined, managed, measured, controlled, and effective. Crosby's Quality Management Maturity Grid (QMMG) is the pioneering example of a maturity matrix, advocating a progression through five stages: uncertainty, awakening, enlightenment, wisdom, and certainty. Uncertainty means *'We don't know why we have problems with quality'* whereas at the other end of the scale certainty stands *for 'We know why we do not have problems with quality'*. Maturity matrixes are improvement tools as well as assessment tools [17], where assessments help to better understand how far people and the organization have improved in reaching wisdom and ultimately certainty.

7. Involve people

Before initiating a project on quality management commitment of top management was required. Implementation needs regular reinforcement of this commitment.
Although continual improvement and effective handling of internal and customer complaints can well be supported by software, it is the organization that does it. Culture must be quality-aware, people must believe in the value of continual improvement and be curious for the needs of customers. Last but not least: employees must feel safe to work on continual improvement. Many improvements are upon 'something' not being optimal or erroneous. Signaling such issues and improving them needs a culture of transparency where improvements are appreciated and openly

visible for the staff. If, however, management penalizes persons or departments for an identified non-conformity, instead of providing the means to improve so that the same issue doesn't occur again, no one will feel free to signal issues and propose improvements. Instead, time will be wasted to 'repair' issues (if possible) without management knowing.

A special issue here are cultural differences between countries, populations, ethnicity, gender or language groups. Implementation of a quality management system needs to take such complexities into account. Especially for work instructions they need to be understood in complete detail by the employees that need to use them. Language confusion and different standards used in parallel in companies, like e.g. centimeters and inches, can lead to important errors. Trompenaars & Hampden-Turner [18] distinguished four types of corporate cultures, closely related to national differences. Especially for multinational organizations the lesson is that what works in country A does not necessarily work without serious modifications in country B.

8. Ensure competence of persons

Especially important in the new ISO 9001 standard is emphasis on training & competency of persons. In the Crosby matrix the notion of "We don't know why we have problems with quality" is often associated with the recognition within organizations that processes, procedures and work instructions have been described, but that in real life these are not known by the persons who execute the work. This is a symptom of a disconnect between management and the work floor.

Management must provide the support that ensures that employees gradually acquire all competencies to reach a full job potential. The set of competencies relevant for the organization is a combined effort of employees and management, where management acknowledges and validates that roles have been well defined and that the roles in the organization are understood by the employees. In reverse, employees should acknowledge that they understand why tasks belonging to a role are to be performed in the context of the whole process. Especially tasks that do not immediately serve a clear purpose (or add value), but that are relevant later in the process or in other processes need to be well understood by employee and manager for optimal performance of the organization.

9. Improve continually

Implementing a quality management system can be handled as a project. The project then delivers a functioning quality management system for the organization. Transfer to the line organization is a challenge because firstly management needs to be involved and the pitfall of delegating should be addressed and secondly, continual improvement efforts are needed.
Audits are a key tool to monitor functioning of quality management. Especially important for continual improvement is that (internal) auditors are not normally working in the same environment, like the department, process or location. Auditors have a 'fresh look' at the activities they audit. If audits are performed by external auditors, for instance from an ISO 9001 Certifying Body, these auditors are impartial and the 'fresh look' aspect will even be stronger. Additionally, external audits are towards a standard (like ISO 9001: 2015) and provide a level of benchmarking.
It cannot be repeated enough: quality management must remain a top management priority; top management must be involved and support continual improvement initiatives. Such continual improvement initiatives result from audit findings, from internal and from customer complaints, from process measurements, from identified nonconformities, from customer feedback and market studies, and last but not least from proposals to improve where nothing is apparently wrong. This last group of improvement initiatives encompasses the 'preventive actions' described in the earlier ISO 9001: 2008 standard. Well-maintained risk analyses are important here; periodical reviews should show that the more important risks have been addressed, leading to a

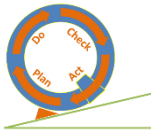
new prioritization of the remaining risks. Also, initiatives to improve workflows, like removing irrelevant steps and better aligning interdependent processes fit in this category. Lean production and lean consumption [19] may be ultimate goals.

And now? Is it enough?

As already mentioned, building and implementing a quality management system based on the ISO 9001 core, with clear processes detailed into procedures that define everyone's daily work is quite an achievement. It creates a solid structure for continual improvement. Better functioning primary processes, fewer complaints and more satisfied customers are the immediate benefits of well-functioning quality management.

But, is this enough?
Is it enough if an organization is quality-oriented, with a well-working continual improvement, supportive and involved management, reaching 'wisdom' or even 'certainty' in Crosby's quality management maturity grid (QMMG)?
The answer is no if this all is restricted to the inside of the organization, or, even more limited, to its primary process. Customers may to some extent be involved, and probably critical suppliers are, but if the main other aspects linked to society, environment and sustainability are not incorporated, the added value of quality management will decrease over time. Other organizations will do better, and your organization may be driven into obsolescence. This is not to suggest that building a solid quality management system to achieve good quality management isn't important. Operational excellence is important for every profit and not-for-profit organization: don't waste time, energy and materials. But much more is at stake without the much wider scope of reaching a new long-term sustainable balance.

EFQM, briefly discussed in the chapter 'Other toolboxes', strongly links excellence to sustainability. Its vison is *'A world striving for sustainable excellence',* and creating a sustainable future is listed as one of the eight fundamental concepts of excellence. In its Global Excellence Index [20] EFQM lists, amongst others, industries in the automotive, aerospace, energy and minerals/mining sectors. Typically, industries in these fields are more associated with exploiting and depleting natural resources than that they are close to a zero ecological footprint, as part of a sustainable future. They may do better than before but have a long way to go before becoming part of that sustainable future. The challenges to reach sustainability are immense. Reversing the depletion of natural resources, addressing global warming, changing business models from profit maximalization for owners/shareholders into long-term sustainability: just some aspects to be solved, simply to avoid that we become part of No Future, Inc., a term coined by Philipp Blom [21]. He describes Western societies as *'intent on avoiding the future and living in an eternal present. Climate change and digitization are destroying this self-imposed stasis and this constellation creates dangerous energies for democracy, liberal ideas, and human rights.'* Organizations must break the *'eternal present'* status and really work towards the future because (citing Blom once more) *'there is no planet B'*.



Annex 1: Condensed literature review

Estimating the combined benefits of a well-functioning quality management (and also environmental management based on ISO 14001) in an organization is difficult, but studies addressing performance and benefits do exist.

The American Independent Association of Accredited Registrars (IAAR) did a large survey on ISO 9001 certification [22]. Around 2,500 companies responded, 83% were ISO 9001 certified. 96% responded that the (current) certification was a positive experience. The main external benefits reported were improved customer satisfaction (55%) and improved perceived quality (57%). 84% rated the quality management system beneficial (66%) or extremely beneficial (18%) to the organization. 84% reported that the investment in quality management systems had a positive Return On Investment (ROI; 0-5%: 31%; 6-10%: 27%; 11-20%: 15%; >20%: 11%).
Many studies based on surveys have been published, often with a limited scope: a certain type of industry in one country or region. Because of the limitations in the surveys, results often are 'soft': 'it is suggested', or 'our findings indicate' and in the end more questions are raised than answered.

For companies producing products, the classical study of Corbett *et al.* [23] compared 554 ISO 9001 certified companies in the United States with an equal number of non-certified ones as controls; data were from the period 1987-1997. The analysis of data from two years before the ISO certification till three years after the initial certification showed that cumulative improvements in the certified companies were strong and lasting. Over the five years studied, a relative increase in ROA (Return On Assets) of 25% was reported compared to the non-certified firms. For the ROS (Return On Sales) a similar improvement was reported. The average COGS (Cost Of Goods Sold)/Sales quotient decreased by 3.28% in the certified firms compared to the non-certified ones over the same five-year period, a relative improvement of 5%. Corbett *et al.* conclude *'To summarize, firms' first ISO 9001 certification did lead to improvements in ROA, primarily through increased productivity.'*
A comparable study based on 397 United States' firms that had received ISO 9001 certification from 1991 to 2002 similarly concluded that ISO 9001 certification is statistically related to operating performance, that certified firms have a better operating performance and that certified firms outperformed non-certified firms [24].

Later quantitative studies confirmed the outcomes of Corbett *et al.* and added new insights, especially on the importance of continually enhancing quality management systems (or growing maturity of quality management) and the benefits of well-integrated management systems, especially quality and environmental management systems. Some examples follow.

Novokmet & Rogošic [25] found that EBIT (earnings before interest and taxes) and ROA were positively correlated with more mature quality management systems. For their study they approached ISO 9001 certified large-sized companies in Croatia with a questionnaire on quality management system maturity. A 1-5 Likert scale was used for the items that measured the implementation of eight quality management principles (where 1 was "strongly disagree" and 5 was "strongly agree"). Two clusters were created: 52 companies having a more mature quality management system and 24 in the initial stages of quality management. The questionnaire responses were compared with financial data over 2010-2014.

Published in 2016, but based on data from 1996-1998, O'Neill et al. [26] found positive relations between quality management systems and the financial performance of small Australian manufacturing firms (up to 99 employees). Performance was measured as ratios based on capital

assets and on total sales, both divided by the total number of full-time employees. Data were collected through the Australian Bureau of Statistics; answers on the quality management systems were collected via Likert scales.

For a sample of 50 Catalan companies, questionnaire answers (again Likert scales; year: 2010) and financial data were combined to analyze the integration of ISO 9001 and ISO 14001 [27]. A significant link was found between the integration level of the two systems and financial performance of the companies: better integration of especially the procedures is positively correlated with better financial performance.

In an extensive literature review Bernardo et al. [28] conclude that *'organizations that integrate their management systems benefit from the improvement in efficiency arising from costs savings, better internal organization and improvement of image'*. Also, they stated: *'when a firm really applies the quality system underlying the standard, and there is a real commitment to quality and to the environment, that is, when the standards are internalized, there is an increased likelihood of attaining the benefits listed, including the financial ones'*.

In summary, it can be expected that after the implementation of a quality management system especially the supply chains gain several percent in efficiency. Better functioning supply chains, fewer complaints and more satisfied customers are proven immediate benefits of well-functioning quality management structures. It is also clear that combining certifications, especially ISO 9001 and ISO 14001, has a synergistic effect.

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Annex 2: The IDEF0 methodology; an example

To illustrate the logic and elegance of outlining the processes of an organization using the IDEF0 methodology, this annex provides a more complete overview of an imaginary production company.

Firstly, the entire organization is represented by one box (the A-0, or A minus-zero chart). At the next level the organization is split up in its main functions (the A0 chart).

The viewpoint of all IDEF0 charts presented here is *information*. In some cases, it can be relevant to develop models for other viewpoints, such as materials/goods/products, or for instance, financial. Different models can co-exist. [2]

Two boxes in the A0 chart have been further detailed:
A1: *Develop and execute strategic plan,* and
A4: *Produce products*.
In any organization it is more than likely that also A2 (Develop products), A3 (Manage products) and A5 (Sell products) do at least need one more level of IDEF0 charts.

A1 and A4 were chosen because of two essential quality management- and quality-related points. Within chart A1 a box A14: *Continually improve* has been incorporated to show the position of a typical central quality management or quality assurance group. This group is very different from quality control, visible in chart A4 as A45: *Control quality*. [3]

[2] See also this guide, chapter *Enterprise, Process and Function Mapping*
[3] See also this guide, chapter *Definitions: Quality, QA, QC, QM*

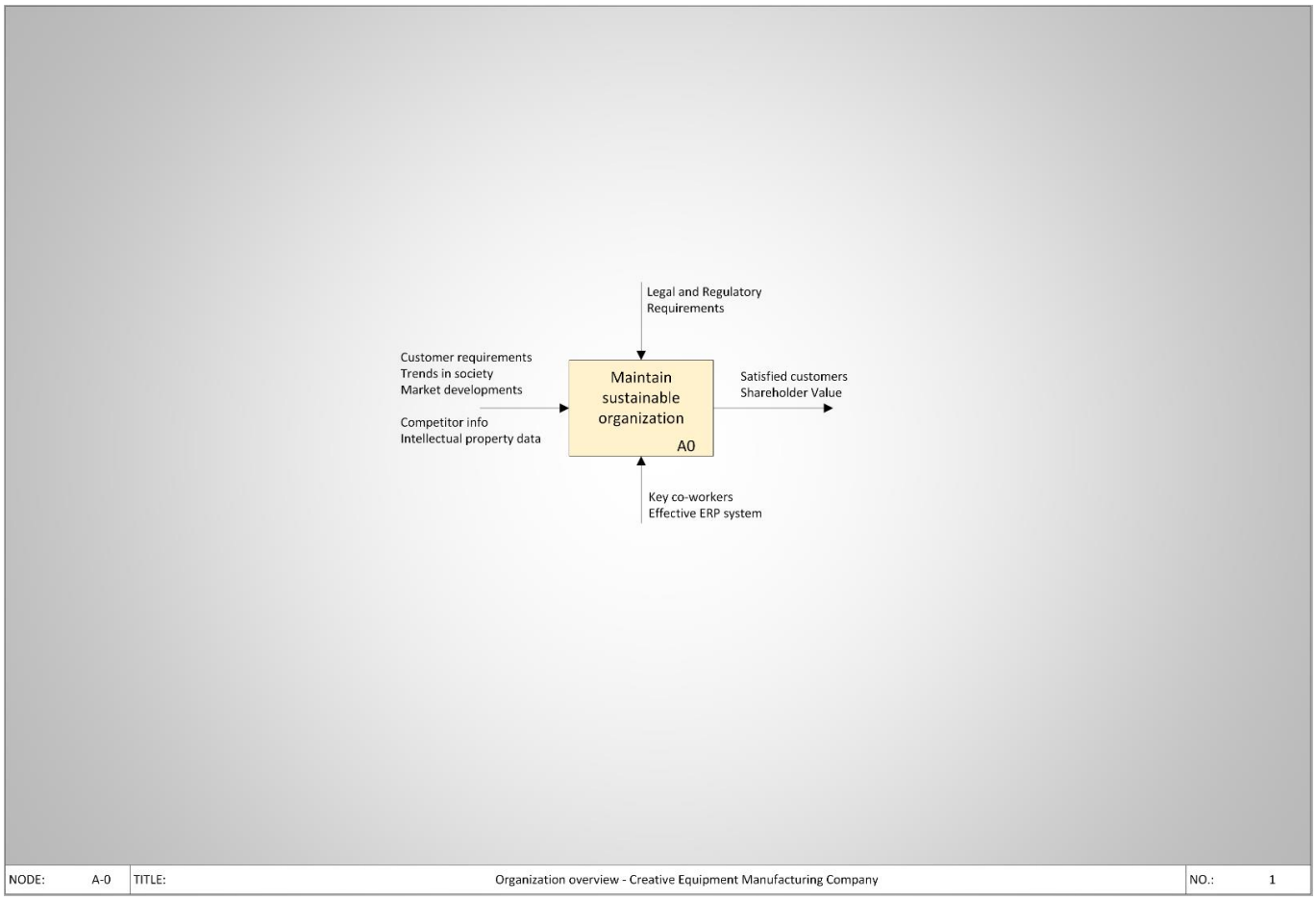


Chart A-0

A complete IDEF0 chart of an entire organization (enterprise, company, non-profit organization). The activity at this top level is being and remaining a sustainable organization, with client demands as input (and probably other inputs as well) and happy clients and shareholders as outputs. (There may be more outputs.) Key constraint is the strategy of the organization. Without its co-workers the outputs cannot be achieved.

The top level IDEF0 chart is coded A-0 (A minus zero; this is the node number of the chart). It describes the entire organization in one box, coded A0 (A zero).

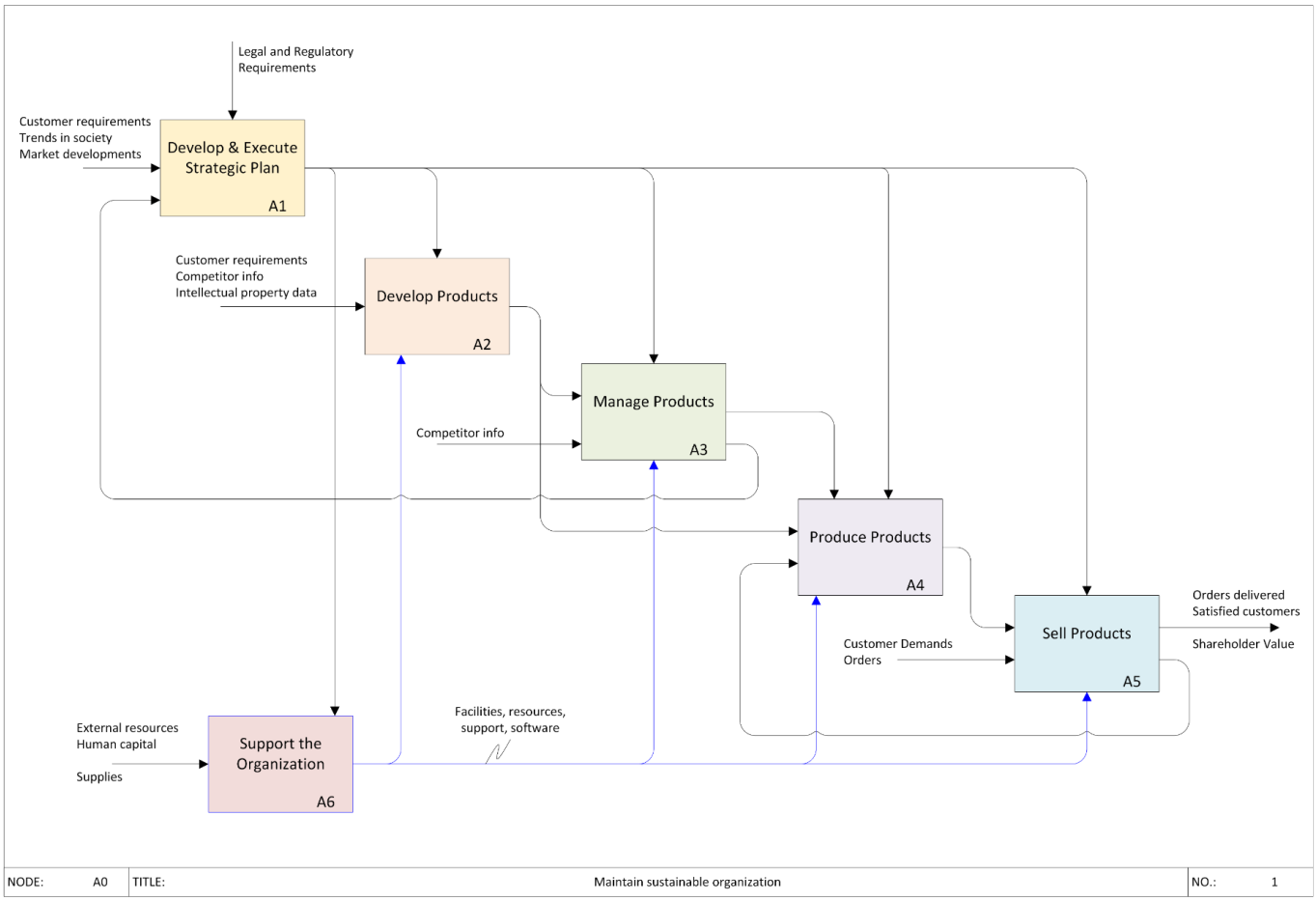


Chart A0: Maintain a sustainable organization

The next level chart has node number A0. It is the highest-level breakdown of the organization in its main functions. The boxes depicting these are subsequently numbered from A1 to A6.

The example shows an equipment production company with the ability to develop its own innovations and a sufficiently complex product portfolio to need product management.

The 'primary process' of the organization is the top left to bottom right series of boxes, from strategy to sales of the developed and produced products. All secondary processes are combined here in box A6: support. This box here takes care of the requirements needed in the primary process, from facilities to IT infrastructure and software.

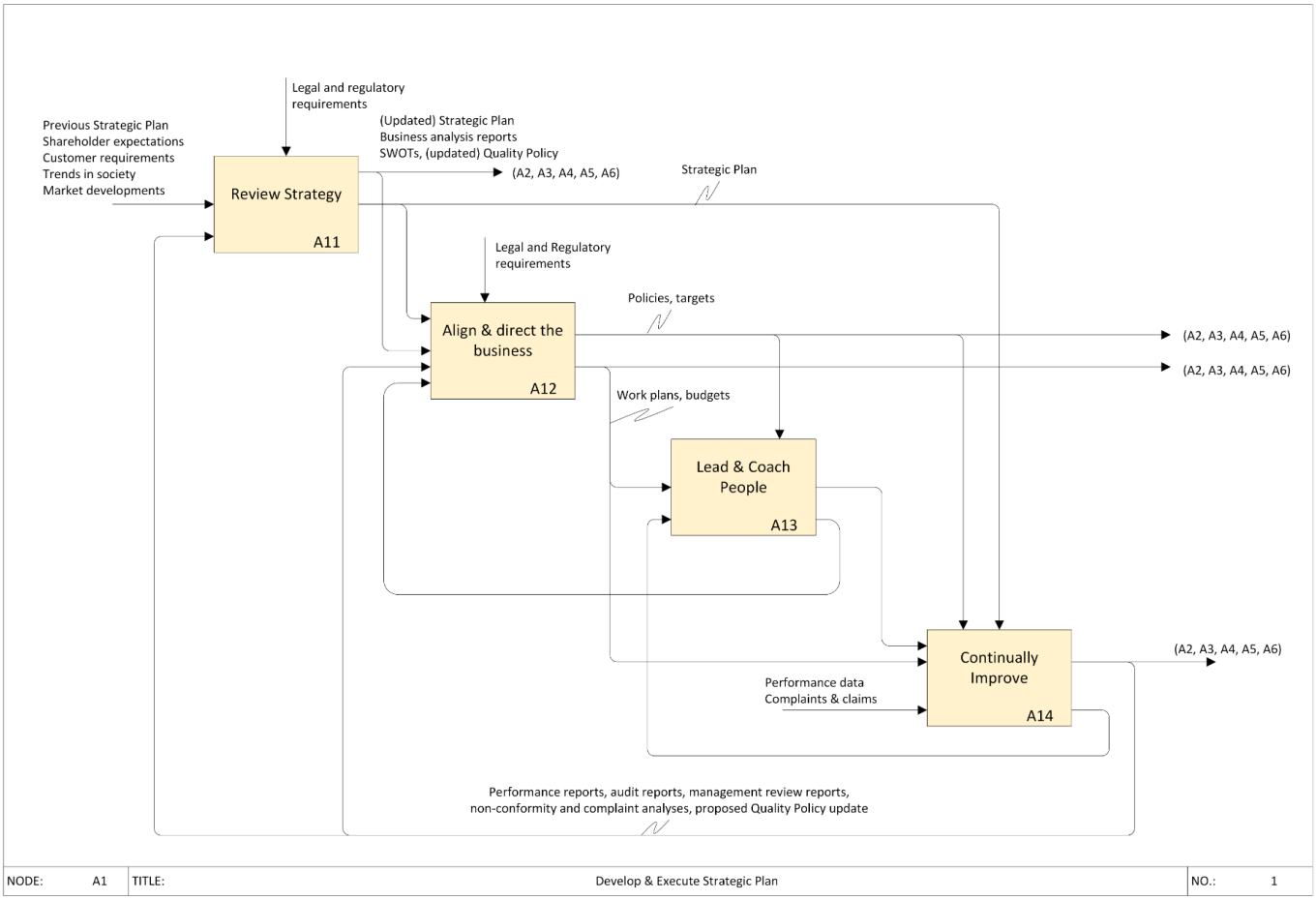


Chart A1: Develop and execute strategic plan

A strategy needs to be reviewed and adapted to remain relevant. And it should be translated into running the organization, creating incentives and providing structure and the environment for enhancing performance of the people associated with the organization.

Quality management is positioned in chart A1 (box A14: continually improve), as it is a top management responsibility. (Quality control is shown in chart A4, box A45.)

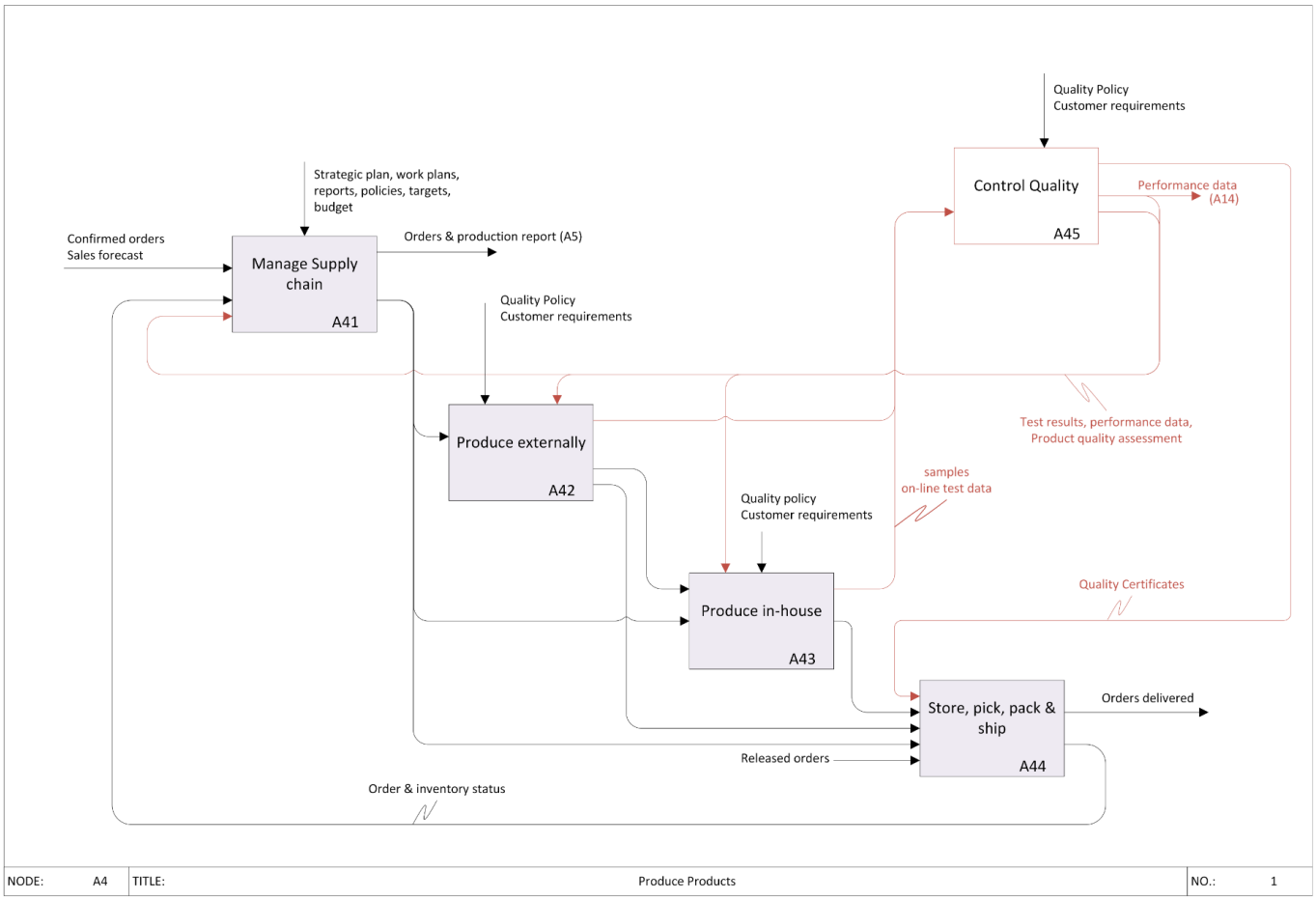


Chart A4: Produce products

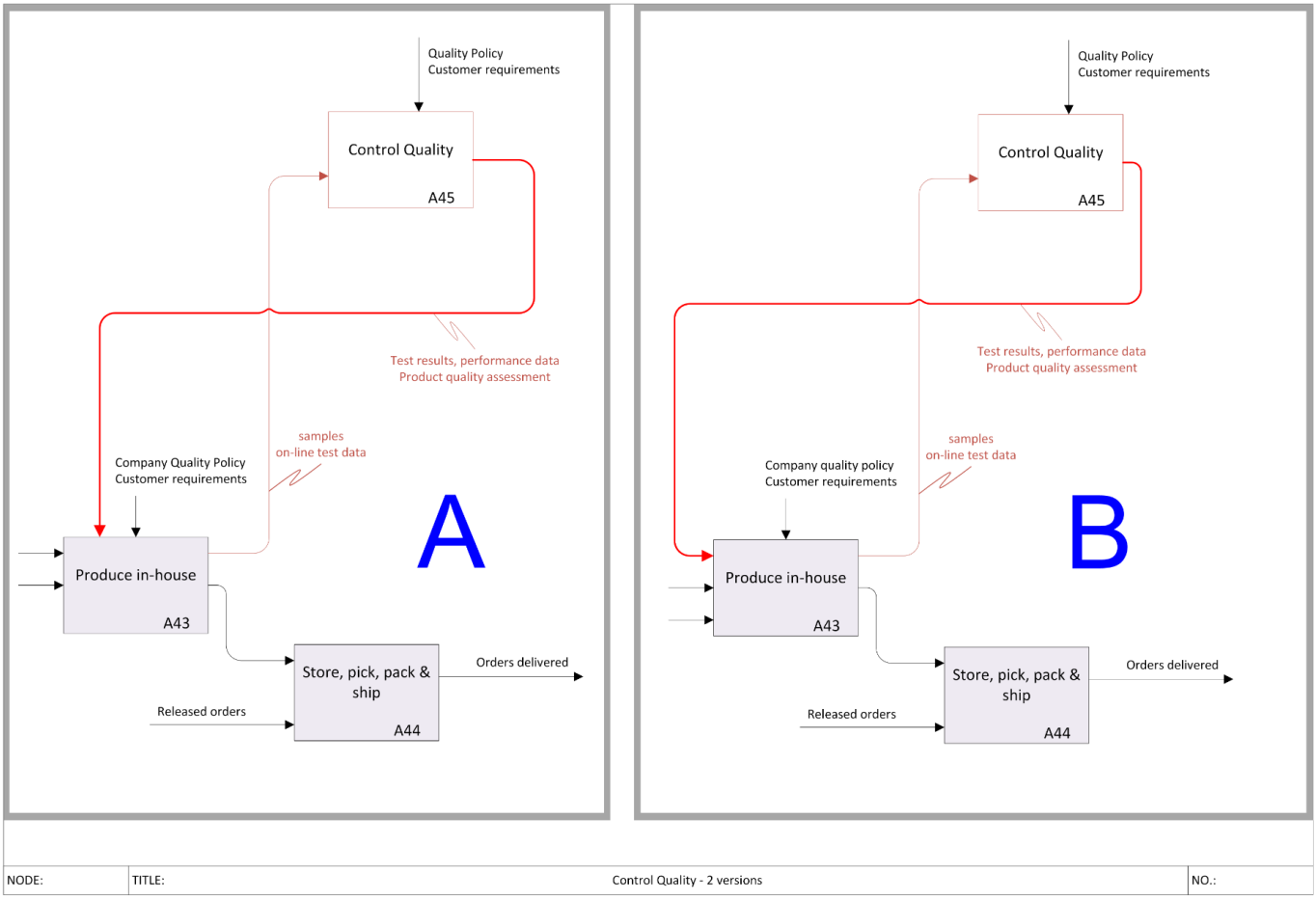
Production here is shown as either external or in-house production, governed by supply management and with one central department for storage and shipping the packaged products.

Important is the place of quality control (box A45): its results are constraints for production. Quality control tests and, based on the requirements, decides: a product either meets the defined requirements (so it can be shipped), or it is rejected (resulting in repair, re-working, or even another product to be produced). Quality certificates are an input for the shipping department: that is where the documentation for each shipment is completed.

See also below for this structure compared to an alternative where the output of 'control quality' is presented as an input for production.

A further breakdown of some of the IDEF boxes in chart A4 is thinkable, for instance for A44 if the relations between storage/warehouse, packing and expedition are sufficiently complex. Typically, undertaking the exercise helps to understand whether creating a further chart to breakdown an IDEF box is relevant. The further breakdown should not be done if the resulting chart becomes too simple: the output of the first box is the input for the second box, the output of the second one the input of the third, and so forth. Instead of this IDEF0 chart a RASCI-based procedure should be written. [4]

[4] In this guide, chapter *RASCI and other models*, Figure 8, an example of a procedure is presented which is linked to box A4. For a simple production company (one site, only in-house production) this could be the case. In this Annex a more complex company is presented; therefore, box A4 is further detailed into the chart A4 above, which dictates that here the procedure shown inn Figure 8 would belong to box A43.



An important detail of chart A4: Produce products

Quality control as a process that creates decisions (A), or as a process that provides input to Production (B).

In the preceding chart A4 the output of quality control is presented as a constraint for production. This is the desired situation where quality control is acting impartially (situation A in this chart).

Situation B is fundamentally different: The test results are inputs for production (A43: Produce in-house) and it is *within* this process that the decisions are made to approve or reject the products.