MASTER

Selection of a root cause analysis tool under a contingency based approach

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Award date:
2012

Eindhoven, August 2012

Selection of a Root Cause Analysis Tool under a Contingency Based Approach

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in partial fulfilment of the requirements for the degree of

Master of Science
in Operations Management and Logistics

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TUE. School of Industrial Engineering.
Series Master Theses Operations Management and Logistics

Subject headings: Root Cause, Contingency Based, Selection Methods.

Contents

Acknowledgements

This report represents more than one and a half year of hard work, since the literature review to the final report. I want to give special acknowledgment to my supervisors both in the TU/e as in Philips Healthcare, which made possible the realization of this, my thesis research.

To Jos, I really appreciate the trust given to me while offering me the project in our first meeting. I did my best to fulfill the first expectations. It is a long way since the beginning of the project, but all those guidance meetings that offered me new perspectives and learning were invaluable for the development of the research. Especially when it came to offer the helicopter view for the general outline that best fitted to report my findings.

To Rob, I want to thank for the conversations over the detailed ideas developed throughout the project. I found very interesting the ease to synthetize the content of the research that helped me to get back in track when not so relevant aspects where making noise in the report.

Last but not least, I want to thank Jan, for all the trust placed in me and my project, it was very refreshing to exchange ideas regarding the project. It was of great motivation to whiteness the enthusiasm and interest allocated to this research. I appreciate also all the support and guidance offered so I could find my way in the organization. Especially through such a period of time filled with uncertainty and changes.

I want to thank to all my family, because the distance has not been an impediment to demonstrate the care and support.

I want to give special mention to my parents Álvaro and Magdalena. You always encouraged me to follow my dreams and give all the effort possible to achieve them. This new step I take is product of those lessons. I have no words to express how much I thank to have such supportive parents as you are.

To my brother Andrés, without your love and motivation this work would be even more difficult. Thank you for always being concerned about my work and how am I doing.

I want to thank my friends, source of energy to achieve this goal. Thank you for your company and motivation.

-Daniel Vallejo González-

Abstract

This research investigated the procedures of the practitioners in a software-intensive product organization for the application of the Root Cause Analysis among its processes. Having the as-is situation delineated, the literature best practices were confronted with the observations and the gaps between these were identified. These gaps were afterwards tried to be closed.

The result is a two-steps process improvement for the defect handling process, in which the decisions and activities needed to support a root cause analysis were settled inside the process definition, having this way a structure that supports the decision making for the applicability of RCA on problems.

To apply the RCA, a set of tools is proposed. Each of these tools help to attack different problems under different conditions. To define the conditions that promote the utilization of a particular tool, three activities were done. First it was classified the project types in the organization. Second, the tools were divided in three categories. Third, a relationship was created among the project types of the organization, and the categories of the tools.

The purpose of such relationship is to guide and encourage the practitioners in the utilization of the tools that offer advantages according to each problematic situation. A contingency based mindset; this means, to recognize that "one-fit-all" tools could be useful, nevertheless it is possible to find better performances when using a tool designed for a special purpose.

Additionally, it is suggested further studies for the development of a Lessons Learned Organizational Tool, completing with this the ultimate objective of achieving continuous improvement by means of not only corrective activities, but also performing defect prevention activities.

In summary, this research confronts the best practices of the literature to the current practitioners usages, aim to close the gaps by the reformation of processes. It guides through a structured decision making for application of RCA, orientates on which tool enhance results based in a contingency approach, in parallel, offers to the organization a handbook for the utilization of the tools, and finally, promote the development of a transversal communication tool to share Lessons Learned.

I – Introduction

1.1 Introduction to the Root Cause Analysis

Every day, organizations face difficulties to achieve their goals. These difficulties need to be overtaken to deliver the final product or service intended for their customers. Sometimes, the need to deliver provokes a sort of rush to repair an undesirable effect on the product, even though the same effect is found on every unit of the items produced. This is done because the rush for delivery made the organizations think that to attack the effect directly is faster, nevertheless this generates permanent rework, and loose of time on re-inspection.

The Root Cause Analysis (RCA) finds why the effect occurred, and therefore points what situation to change to avoid recurrence of the problem. It can be used as a problem prevention method that promotes corrective actions to fix underlying causes of a target problem (Lehtinen, Mäntylä, & Vanhanen, 2011).

When a problem is detected in the product, it is analyzed what section of the process was responsible and under which conditions was the defect introduced. This gives important information to improve the conditions and tasks of the process, therefore avoiding the occurrence of such defect in the future.

The idea just explained is quite simple, but the task behind it can be rather difficult given the variety of processes restrictions, interactions and conditions. These difficulties can be attacked thanks to the availability of different kind of tools to perform the RCA.

The purpose of this research is to develop an approach that based in the classification of the problems detected on the development process of the product, helps to select the tools needed to find the root cause (RC).

After the RC is found, and the problem solved, it is recommended to share the new knowledge with the people inside the organization that could face a similar problem (transversal learning). This topic is suggested as a further research topic, since the scope of this research did not consider it.

The approach will help to the organizations that are currently using RCA, but need a structured manner of doing it.

1.2 Introduction to the Company

Philips is an enterprise founded in Eindhoven in the year of 1891. Headquartered in The Netherlands, employs approximately 122.008 employees[1] in more than 60 countries worldwide.

Philips Healthcare Nederland It is divided in different business units and departments. This project was held on the MRI Systems department which belongs to the Imaging Systems and is located in Best, The

[1] (Koninklijke Philips Electronics N.V., 2012)

Netherlands. The project was developed under the Business Improvement – R&D Excellence unit, being supervised by J.H. van Moll.

The interest of Philips for this project is triggered by the need of improving the root cause analysis capabilities by having them well defined and standardized, by introducing a relationship between the problems that can be solved with specific tools, as well as helping to introduce a new culture of collaboration when trying to solve problems and sharing experiences.

1.3 Introduction to the Current Situation

Currently, Philips does corrective and preventive actions (CAPA's) in which defects are identified and their RC is investigated. Moreover, the defects found as part of the test activities are also assessed and, if required by regulatory rules, follow an RCA.

This procedure for defect handling and the root cause analysis can be improved. Even though the defects are analyzed into depth, the tools and method used to analyze them is often selected arbitrary.

Currently there are traces of when an RCA has to be done, and where to report the root cause. Nevertheless there is not in place a structure that establishes a formal methodology for RCA; this can provoke variation on the handling of problems, and this affects the outcome of the investigations.

1.4 Introduction to the Problem

Regarding RCA, there are only two tools used in the organization, the fishbone diagram and the 5 whys. Even though these are valid tools, is not ideal to use them for all the variety of defects that can affect a product or process. Moreover, pre-identified characteristics to suggest causes of problems are not used, and most of the times it is not possible to establish a meeting with the different stakeholders needed to discuss the problem.

Along with that, whenever a solution is found for a specific problem or defect, it is hardly spread around the organization and communicated directly to peers that might face the same problematic. A register with all problems, potential root causes and solutions does exist, but is not realistic to expect that the product or process owner searches among the immense amount of information to find if the problem he is facing has already arose in some other place or project. It is even less realistic to expect to find in that data a potential solution for his or her problem.

The theory developed for this project was fine-tuned to fit inside the organization. The main purpose is to allow a structured analysis of the defects found at the *Project Realization* stage of the product development, to be more precise, in the *Validation and Transfer* phase. All this before the product lifecycle reaches the *Release for Limited Delivery* (RfLD) milestone as it is shown on *Figure 1 Product Development Phases*.

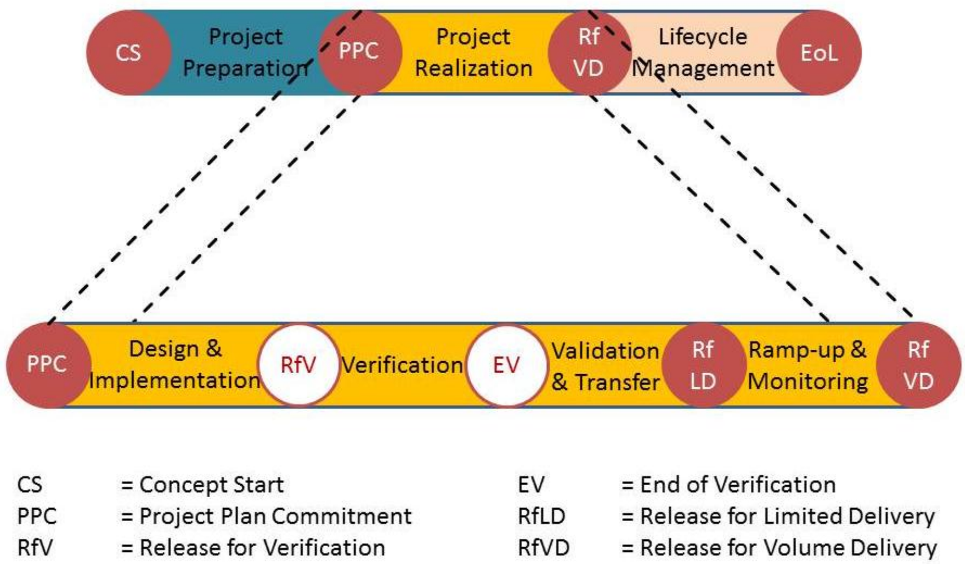

Figure 1 Product Development Phases.

1.5 Research Goals and Research Questions

This section presents the questions to be solved, and aims to establish clear goals and scopes for the research.

1.5.1 Goal

The goal of this project is to develop an approach that offers a guide on the selection of the tools for Root cause analysis deployment.

1.5.2 Sub Goals

This sub goals help to visualize the steps needed to succeed on the fulfillment of the goal.

Short-term Goal

- To give theoretical grounds to the RCA.
- To establish the needed contributions from the product development process for the approach
- To define outputs of the approach

Midterm Goal

- To identify the interaction of the approach in the processes of the organization
- To define information flow for the approach
- To define stakeholders according to the approach

Long-term Goal

- To analyze which are the factors to influence the output of the approach
- To adapt the approach to the processes of the organization

- To validate the approach with its organizational stakeholders

1.5.3 Research Question

The following are the research questions, which by being solved will offer the general summary and ultimately the conclusions of this document.

1. Why is the RCA approach needed?
2. What is the RCA approach?
3. How will the RCA approach perform in the organization?
4. How can an RCA approach be successfully embedded on the product development process of a software-intensive product organization?
    a. How will the approach be used by different parties?
    b. How will the approach interact with the product development process?
        i. What information does the approach needs from the PDP?
        ii. What kind of defects will the approach be concerned with?
    c. How the result of a failure resolution of one project will affect the rest of the projects?
        i. How will the feedback loop create process-broad knowledge? (instead of project-broad knowledge)
    d. What are the guidelines for the approach implementation in the organization?

1.6 Route Map of the Report

This report is organized in the following way:

The introduction just presented as *Chapter 1* gives the reader the information needed to be familiarized with the topic of development, the organization where the project has been held, the current situation on the organization and the description of the problem that is aimed to eliminate. After this, the reader is presented with the research goals planned to be fulfilled with this project. In the last part of the first chapter presented are the research questions that will help to guide the project.

The second chapter discovers the practical purpose of this project and details its execution. It is in this part of the report where the methodology will be presented.

The third chapter presents the analysis done through the project. It will include the best practices found in the literature, the current as-is situation in the organization, and a confrontation between this two realities.

The fourth chapter is dedicated to the design of the proposed solutions and its explanation. The fifth chapter presents the validation of the proposed solutions with the potential stakeholders of the outcome of this research.

In the sixth chapter, conclusions are drawn regarding the content of the research project. It also offers recommendations for further research.

II – Practical Purpose of the Project

The following is desired to be solved by this project:

1. Identify the need to do root cause analysis according to the Literature
2. How to do root cause analysis according to the best practices found on the literature
3. How to apply the best practices into the organization

2.1 Explanation on the Project

The purpose of this project is to propose a guide to improve the manner to deploy root cause analysis, and adapt it in the *project realization* phase of the MRI Systems of Philips Healthcare. The final purpose is to make it fit to the processes done in the daily practice.

2.1.1 Project Execution

Once having clear the goals and research questions, now the execution approach of the project shall be defined.

The main activities since the beginning of the project are:

- An extensive literature research was the first step to learn about the best practices and theories. At this stage, conceptual models and basic ideas of the structure of the approach were drafted.

- Immersed in the host organization, interviews and research helped to clarify and learn about the ways of working, organizational structure, kind of products, projects, processes, as well as the kind of problems faced.

- The confrontation of the previous two realities was done. By identifying differences between practice and theory, it was intended to shorten (or close) the gap between them, therefore the process design improvement and the adaptation of different activities to fit both the organizational reality and comply with the theory best practices.

2.2 Methodology for the Research

The methodological process for the research consists on the following flow[2].

1. Finding of theories on the literature regarding the deployment of the specific section
2. Understanding of the way it is done on the practice
3. Confrontation of those two realities

[2] The Methodological flow algorithm was reasoned from the explanation of Rob Kusters for what is the best way to implement the literature knowledge in this kind of assignments. The explanation took place on the revision meeting of March 15, 2012.

4. Establishing requirements for each section given the differences between these two realities
5. Doing a trial on the requirements developed
6.
    a. If the Requirements trial is passed, then the processes of each section should be designed.
    b. If the requirements trial is not passed, then new requirements should be developed (return to step 4)
7. After the design of the process, these should be implemented

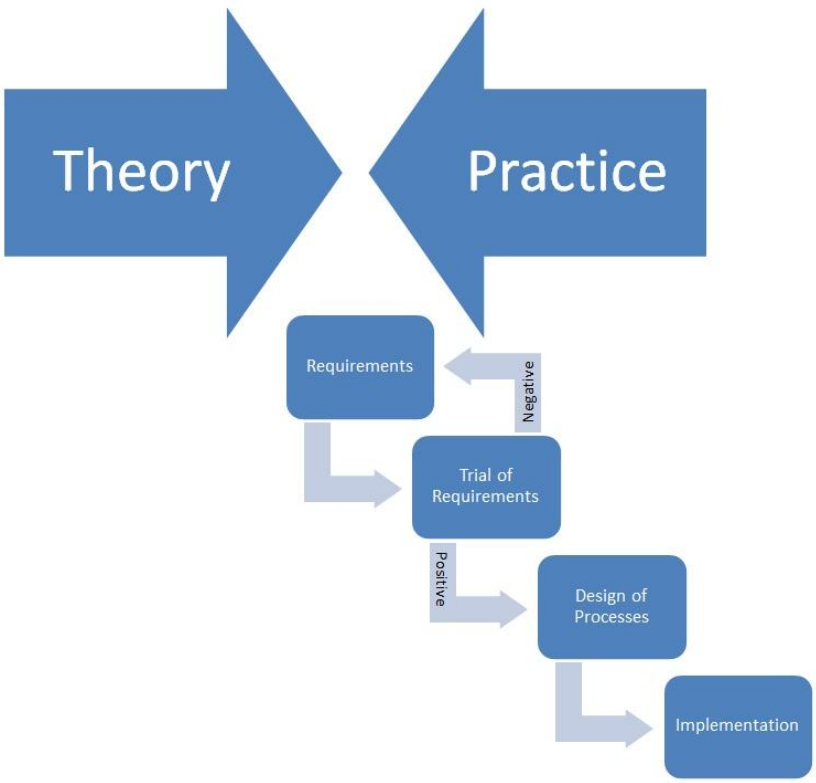

Figure 2 Methodological process

The objective of the project is to deliver a functioning structure that enhances the defect management process in the organization by uncovering the root causes, and by reducing the probability of defect repetition.

The second front to develop this project, called '*Practice*', is how things are done at the organization. This will help the research to be relevant for the organization by allowing the theoretical knowledge be molded to fit the practices of the organization.

It is important to mention that a critical eye is necessary at the time of deciding what part of the organization should mold the theoretical knowledge, and what part of the organization should be modified to embed the new structure.

Given the scope of the project, the seventh point of the Methodology could not be included in the research. Nevertheless, a light validation was done with the persons that would be affected by the implantation of the current research at the organization. The results are shown in section *Validation Conclusions of RCA Pilot Session*.

III – Project Development

The third chapter is advocated to explain the theoretical grounds and orientations followed during the project. It also analyzes the practical situation prevailing in the organization at the time of the project.

The sections *Best Practices of Literature regarding RCA* and *Details of the RCA Tool Selection Approach* show theoretical information about the best practices to implement RCA in an organization. The section *Synthesis of the Best Practices Towards Applicability* offers a model that synthesizes the best practices and explains its main characteristics. That section also explains important aspects of the literature for the enhancement of the quality of products and processes.

Sections *Current Situation in Philips* shall describe what are the current practices at the organization, explaining the "as-is situation".

Confrontation Result, the last section of this Chapter, explains the results of confronting the best practices with the current situation.

3.1 Best Practices of Literature regarding RCA

The intention of this section is to show the ideas found in the literature that were selected as inspiration and theoretical grounding for the development of the research.

Special focus has been given on the influence that the risk analysis can have into the quality of the software-intensive product development process. (Verdon & McGraw, 2004) propose three important times when the risk analysis should be done (See *Figure 3 The software development life cycle* ; before and after the design milestone, and after the test results. This agrees with the idea of how organizations should focus on the testing procedures to avoid costs due to misclassification of compliance or noncompliance of the software (Misirh, Bener, & Turhan, 2011).

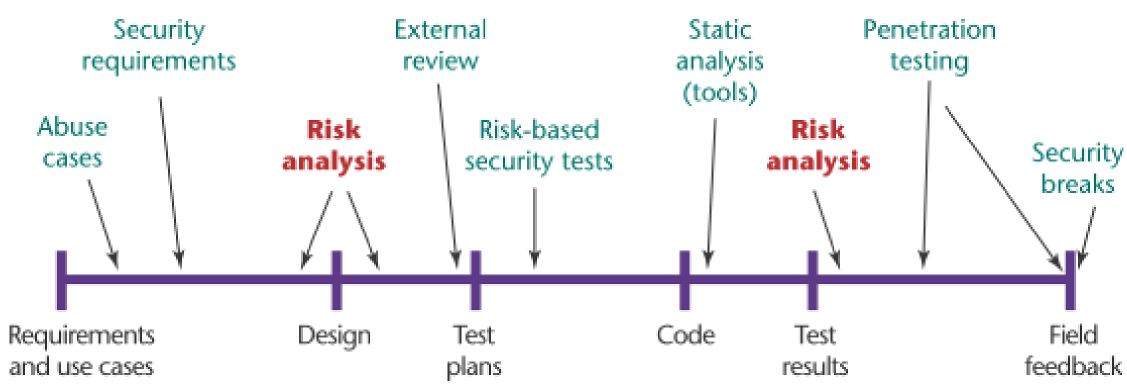

Figure 3 The software development life cycle (Verdon & McGraw, 2004)

(Son, Na, & Kim, 2011) pictured the Samsung's conventional development process, which consists of four stages; 1) Concept, 2) Plan, 3) Development, and 4) Production. The basic Idea of the model is divided in two; first the regular software development process, and second, the information cycle of the problem. Each part is shown on *Figure 4* and *Figure 5* respectively.

It is important to take into account the complete software development process, especially considering the testing procedures, in a way that can be used as a guideline for having a feedback loop, together with a culture that facilitate the usage of RCA tools and problem prevention tools for the process owners.

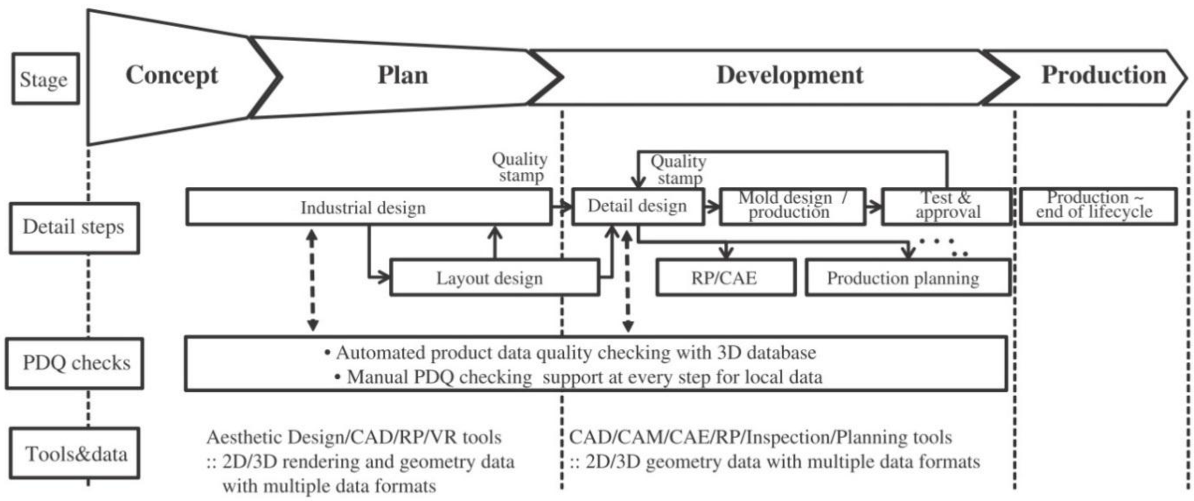

Figure 4 General high-tech development processes and related data flow (Son, Na, & Kim, 2011)

The second idea of the model explains that there must be a flow of information that is triggered by a defect introduction, followed by the subsequent steps until the resolution of failure is fed back to the PDP.

Furthermore, it should motivate the absorption of previous lessons learned to avoid problem recurrence; this can be achieved by the installation of transversal communication of the lessons learned throughout similar projects. The purpose would be to allow new lessons learned be developed and linked to specific situations to be shared with similar projects that have not yet faced such a problem.

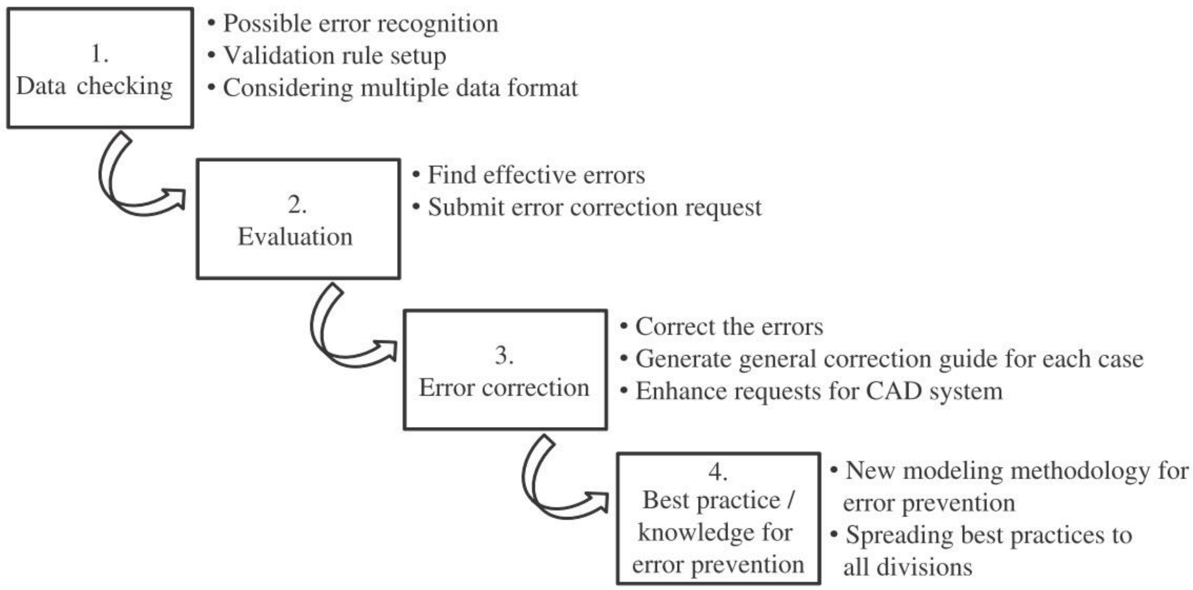

Figure 5 PDQ activities from data checking to error prevention (Son, Na, & Kim, 2011)

In this section of the model, (Son, Na, & Kim, 2011) described a serial of steps to prevent errors. On their proposal (*Figure 5*), they implemented an automated module to find errors on the early stages of the product development lifecycle.

3.1.1 Details of the RCA Tool Selection Approach

In the work of (Shen, Hsueh, & Lee, 2011) a model with multiple factors affecting selection of measures taken can be found. They developed effect measures with associated engineering values that are showed in the following table.

Table 1 Definition of effect measures with associated engineering values (Shen, Hsueh, & Lee, 2011)

Measure	Definition	Implied capability	Engineering value
SEA	Size estimation accuracy	Ability to measure software size	Measurability
TEA	Time estimation accuracy	Ability to predict development time	Predictability
APR	Actual time to plan time ratio	Ability to meet project deadline	Predictability/ controllability
DEA	Defect estimation accuracy	Ability to predict defect frequency	Predictability/ traceability
DRR	Defect remove rate in compile and test phase	Ability to decrease defect in compile and test	Controllability
YLD	Yield in percent of defects injected before the first compile that are removed before the first compile	Ability to control defect ere compile	Manageability
DDS	Number of defects removed per thousand lines of code developed	Ability to decrease defect density	Reliability
LPH	Total new and changed LOC developed divided by the total development hours	Ability to increase productivity	Efficiency
AFR	Time spent in design review and code review as a percentage of time spent in compile and test	Ability to manage risk	Reliability/efficiency

After defining such effect measures, they developed the Plan-Track-Review model that explains which categories from the previous table should be taken into account depending on the variation of the stage and the variation of the level; therefore the following table was developed by them.

Table 2 Stage-wise Personal Software Processes effect indicators on a gradual basis. (Shen, Hsueh, & Lee, 2011)

Stage	Entry level	Intermediate level	Exit level
Plan	SEA	TEA	APR
Track	DEA	DRR	YLD
Review	DDS	LPH	AFR

This model addresses the intention to evaluate different factors to provide most accurate answers. This is relevant to the present research as an approach that can improve the PDP quality.

The contingency concept is the idea of being able to use different kind of resources already specified to given scenarios taking into account different variables. The strength of the model presented by Shen, Hsueh, and Lee is the application of the contingency principle, which in short states that for different situations; different instances (e.g. Techniques, Methods and Tools) should be used. (Cash, McFarlan, & McKenney, 1988)

3.1.2 *Synthesis of the Best Practices Towards Applicability*

In this section the *Defect Introduction-Resolution of Failure cycle* is proposed. It is inspired by the models by (Son, Na, & Kim, 2011). It is important to note that the cycle interacts with the product development process. The PDP is formed by a number of different stages that are interrelated.

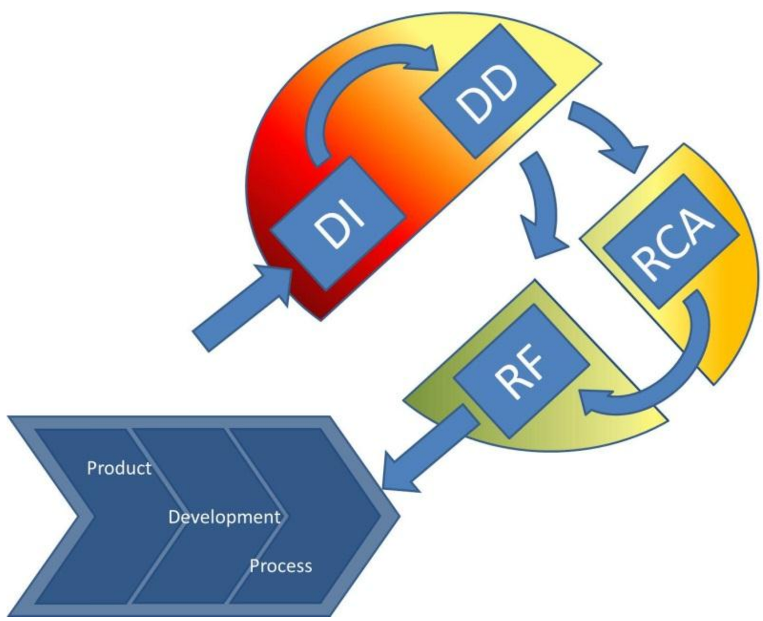

Figure 6 DI- RF cycle on the Product Development Process

This model has a number of key aspects or principles, which are named as follows:

- Cyclical:
  The *Defect Introduction-Resolution of Failure* has a cyclical interaction with the product development process. It does not necessarily (has to) close on the same stage it was introduced. The cycle is triggered unintentionally (by the Defect Introduction) under the assumption that there is no will of any person related to the PDP to worsen its performance. Due to its nature, the PDP is always under the danger of Human Error (Cacciabue, 2004) therefore defects may be introduced in every stage of the development, and hopefully those are detected and subsequently removed by the verification and validation process performed during all stages of development (Jacobs & van Moll, 2007). This means that is a task of the Development Team to close the cycle.
- Problem Identification:
  A mature level on the CMM does not assure a PDP free of problems (Cacciabue, 2004); therefore tools for defect detection (DD) shall be used.
- Stage conscious:
  The main issue is that problems or defects introduced to the PDP should be possible to identify before the testing phase of the process. Otherwise several adverse situations might affect the development process, such as delay, running out of budget because of new problem solving expenses or poor quality product.
- Feedback oriented:
  Once the main causes of the defects are identified, the development team should solve the situation by changing a part of the process or setting a safety measure that prevents the mistake or defect to happen again. It is important to share this development, for example by redoing a FMEA of the new process, moreover, do it including the stages of the process that already existed, not only the new or modified stages, this is because, as mentioned by (Ursprung & Gray, 2010), the interactions between new and existing steps can be missed and may lead to errors.
- Preventive approaches:
  (Ursprung & Gray, 2010) defines two kinds of problem finding tools, reactive as the RCA and proactive, in this category we can find the Failure Mode and Effect Analysis (FMEA). The model tries to illustrate the need of utilizing the previously explained Feedback loop in order to create a preventive culture in the organization.

Besides the important characteristic revealed in the model, the literature also mentions important aspects regarding the enhancement of the quality of products and processes.

- Process overview**:**
  Business activities should be viewed as more than a collection of individual tasks; they should be broken down into processes that can be designed for maximum effectiveness. Using Taylorism to organize work in modern organizations is inefficient since the steps during a business process are related to each other; therefore context information is required during the process. This is the reason why managing by customer-driven processes that cross organizational boundaries is

an appealing idea that has worked well in the companies that have experimented with it (Davenport & Short, 1990) (Weske, 2007).

- Root Cause Analysis:
  Its purpose when analyzing a defect is to find out what happened and its cause. However, if the purpose is to achieve a better system, then is necessary to go further and reflect on what the incident reveals about the gaps and inadequacies in the system in which it occurred (Vincent, 2004). The process to identify the root cause should start with the output(s) of the investigation: Clearly defined problem statement, what information was gathered, results of the reviews of the information, identification of causes, solutions to address the causes, the output of the root cause analysis should be a clear statement of the most fundamental causes resulting in the nonconformity (Global Harmonization Task Force, 2010).
- Differentiation of tools for different projects:
  One of the serious deficiencies in practice that involve both general management and IT management is the lack of recognition that different projects require different managerial approaches. Even at a gross intuitive level, a project classification is useful to separate projects for quite different types of management review (Cash, McFarlan, & McKenney, 1988).
- Lessons Learned:
  To provide the engineers with a tool to assist in ensuring reliable and safe products and processes, grants certain benefits for project management. It emphasizes problem prevention and acts as a catalyst for teamwork and exchange of healthy ideas. It captures engineering knowledge and provides focus for improved testing and development, eventually resulting in increased customer satisfaction. Nevertheless the reusability of this knowledge is limited due to the format in which it is saved; therefore a tool is needed so that engineers can access this relevant information in the manner of queries (Ebrahimipour, Rezaie, & Shokravi, 2010).

The approach aims to guide on the selection of an RCA tool. Moreover, there are points to take into account once the tool is selected. Therefore it is important to establish the best practices regarding the actual work needed when performing a Root cause analysis.

As mentioned above, the objective of this kind of analysis is to find the factors to be solved no only to correct the product defect, but also to avoid that it happens again.

For this purpose, and regardless the tool or method chosen to develop the analysis, the literature offers recommendations in order to succeed in the discovery of the Root Causes:

1. Clearly define the problem and its significance to the problem owners.
2. Clearly delineate the known causal relationships that combined to cause the problem.
3. Clearly establish causal relationships between the root cause(s) and the defined problem.
4. Clearly present the evidence used to support the existence of identified causes.
5. Clearly explain how the solutions will prevent recurrence of the defined problem.
6. Clearly document the criteria 1 through 5 so others can easily understand the logic of the analysis.
   (Gano D. L., 2011)

The literature also explain that the root causes are collected from various stakeholders (Latino & Latino, 2006) (Card, 1998) (Burnstein, 2003) (Rooney & Vanden Hauvel, 2003) through sessions that can include interviewing, questionnaire and brainstorming approaches (Ammerman, 1998) (Andersen & Fagerhaug, 2006) (Burr & Owen, 1996) (Lehtinen, Mäntylä, & Vanhanen, 2011).

It is important to remember that the RCA should first address a specific problem and afterwards explicitly state the root cause found through the analysis done.

It is not the purpose of the RCA to promote specific solutions for a given problem. There should be a clear division; 1) explaining why avoiding the root cause of the problem will prevent future recurrence of an effect, and 2) explaining a proposed solution to be implemented, which goal is avoid recurrence. The latter is related to problem solving, the first one is related to root cause analysis.

These are the principles inspiring and giving meaning to the development of the approach for a well-structured root cause analysis tool selection, included in the defect handling process.

3.2 Current Situation in Philips

To explain the current situation of the practice in Philips, some diagrams that represent their processes are included in this section.

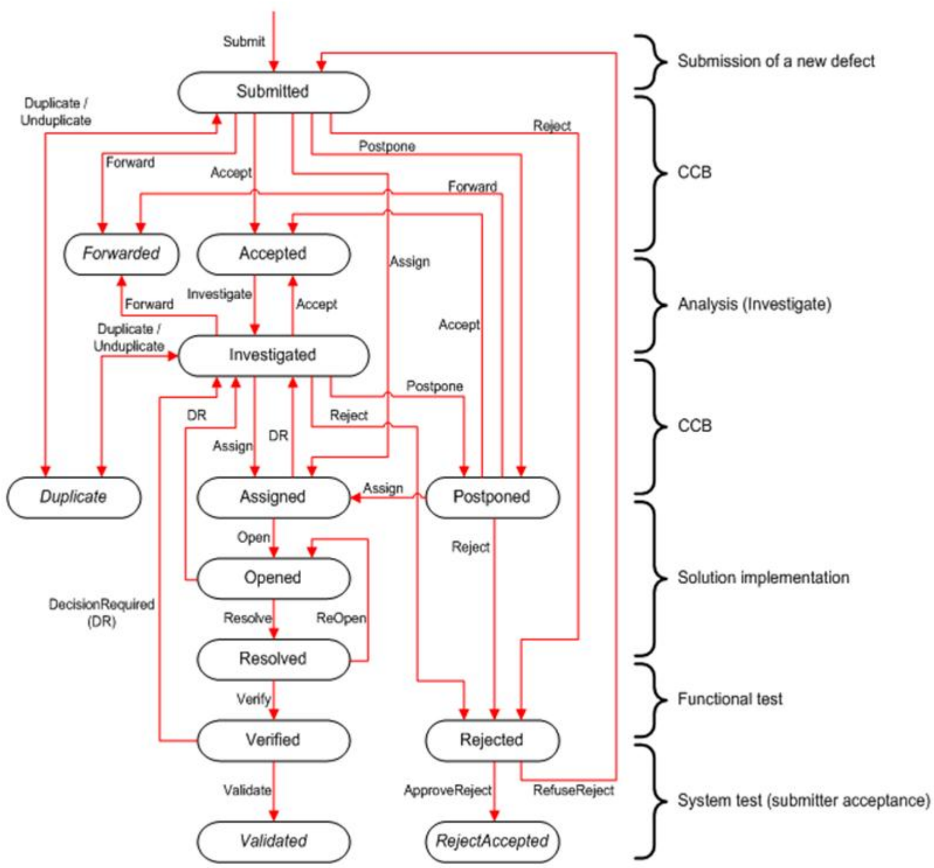

Figure 7 IPR Lifecycle and States (Janssen, 2008)

Figure 7 IPR Lifecycle and States shows all the possible paths for which a defect can be processed. It includes on the right margin the stages (CCB stands for Change Control Board, and represents activities that are done by this entity). Each state is represented by the ovals. Each arrow represents an activity.

Even when it is not illustrated on *Figure 7*, defects are first categorized to be assigned to a competent stakeholder either to analyze it or resolve it. Moreover, to assign priority to the defects, this are scored according to the matrix shown in *Figure 8* in *probability of occurrence* and *impact*.

Impact: / Probability:	Potential Safety Issue: Outcome of the Risk Assessment process	Negatively impacts the product and has no workaround	Negatively impacts the product and has acceptable workaround	Product is operable, issue is annoying/ cosmetic
Occurs every time	Unacceptable Safety Defect	Unacceptable Defect	Unacceptable Defect	Undesirable Defect
May occur	Unacceptable Safety Defect	Unacceptable Defect	Undesirable Defect	Minor Defect
Not expected to occur	Unacceptable Safety Defect	Undesirable Defect	Minor Defect	Minor Defect

Figure 8 Scoring Matrix

The defects already scored and categorized can follow a set of paths that offer different possible outcomes. It is eye-catching about the model shown in *Figure 7 IPR Lifecycle and States* that besides validate a solution, or accept a rejection of the defect, it is also possible to "Forward" the defect, which has not successive action, thus it could be defined as a *deadlock* in workflow analysis terminology (van der Aalst & van Hee, 2002).

Figure 9 Defect Management Process from the "Product Realization Process - Product Defect Management Procedure" (Philips Healthcare, 2012) shows an evolution of the IPR Lifecycle and States. In this evolution the CCB entity changed to DMB (Defect Management Board). An important aspect of this model is the inclusion of the *Risk Assessment* and *Score Defect* activities. Also, it includes the stakeholders responsible for each activity. Nevertheless the evolutions, this model still allows for a defect to be forwarded without any further action specified.

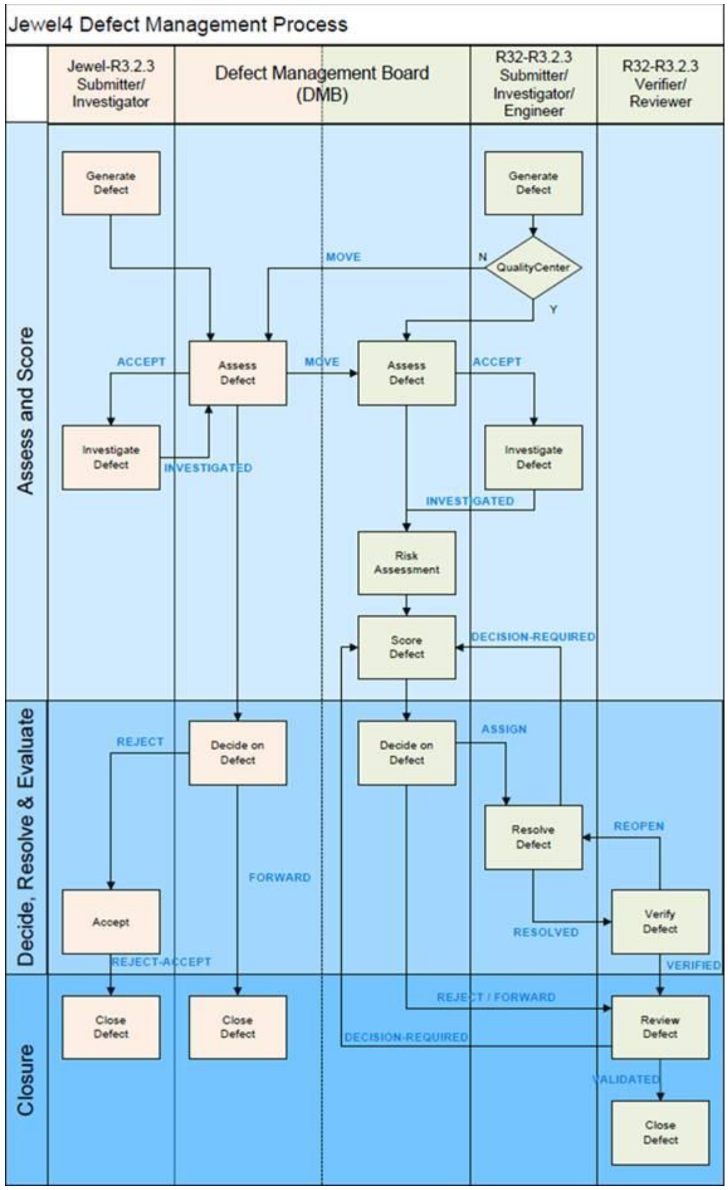

Figure 9 Defect Management Process

For the RCA procedures not much can be described. There is no explicit document that explains which problems are candidates for RCA, even though it is recognized as an activity to be performed by the *Product Realization Process - Product Defect Management Procedure* (Philips Healthcare, 2012). It is not explained who is the responsible to develop the RCA session.

Only two tools are spread around the organization, the Cause and Effect Diagram (CED) and the Five Whys. Nonetheless, there are not lineaments to define when to use each one.

The root cause of the defects is declared on the problem report (PR) but most of the times it is defined by the defect analyst alone.

There is not in place a tool that allows peers to share experience regarding a specific problem of a project. Given the multisite product development team, communication is sometimes not as clear and open enough to inform about defects or bugs when components are advanced to a different location.

3.3 Confrontation Result

In the literature, important principles to improve the quality are documented. The current practice in the organization has ways to work that might differ to some of the principles of the literature. In *Table 3. Confrontation of aspects between the literature and the practice in the host organization*, the confrontation of the two realities is presented.

Table 3. Confrontation of aspects between the literature and the practice in the host organization

Aspect	Literature	Philips Healthcare Practice
Cyclical Principle	Defects introduced on any part of the development process. It is work of the development team to solve the defects on any given stage. Once solved, the solution is fed in the production process	No closure loop on defects affecting the development process of the current or future projects
Defect Detection	Expertise does not imply not to expect defects, tools to detect defects should be employed	Test engineers are the ones in charge of finding defects on the product before it is released to the market. They use a series of predefined tests to try new developments.
Stage Consciousness	Detection of defects on early stages are more economical for the organization	It is intended to filter most of the defects in the test activities. Stages for the defect management process are established
Feedback Orientation	Use the result of the investigations to update the whole procedures, since improving a section without having concerns about its interactions can cause new problems	The solutions for problems are not taken into account for future developments. It is even possible to leave a problem in a "Forward" state, and hardly find a closure for such problem
Preventive Approaches	Tools or methods that help to foresee and prevent potential defects	Few efforts to create a preventive culture are being currently held
Process Overview	To employ a view of multifunctional	The test engineers (principal

	processes, instead of individual tasks	stakeholders for defect detection according to the scope of the project) do have a process overview. It can be exemplified by the fact that they try to understand the situation of the development by having informal chats with the product architects before flagging a PR.
Root Cause Analysis	Foment a Defect Management Process structure that promotes the best practices of RCA and the information it needs. Moreover follow the recommendations for the development of the actual RCA	RCA is done in a basic level. The recommendations are not completely followed. The structure allows a scoring for the problem, but it only serves as a prioritization tool.
Different Tools for Different Problems	It is important to find what tool performs better according to the situation needed to solve	Only two tools are used to solve all the problems that arise and are analyzed
Lessons Learned	Reutilize the knowledge previously acquired by the organization members to ultimately increase the customer satisfaction	Some efforts are done in different sectors of the organization that are not part of the scope of this research, nevertheless those tools are not even well known by the members of the development team (Customer Service Engineering 'Knova' System)

Given the aspects confronted and its essence in theory and in the practice, the following recommendations are given to close the gaps found.

It is important to redesign the *Defect Management Process* to allow, by definition, the incorporation of the RCA. The evolution achieved in the most recent defect management process of the organization, namely the inclusion of the *Risk Assessment* and *Score Defect* activities are heading to a good direction, these should be kept.

One important aspect is to include the Multifunctional team as stakeholders responsible for the RCA activity, according to the literature (Lehtinen, Mäntylä, & Vanhanen, 2011), and make sure that once the process is begun, any path followed lead to a termination. Regarding the triggering of the RCA activity, it should be specified what are the cases that will require of this resource.

For the actual RCA, a larger set of tools is proposed to the organization. This will help to have a better performance to find root causes depending on the variety of problems that could be found.

It is recommended to be aware of the importance of the usage of different tools for RCA, having in mind the need for a structure to select among tools. The models shown in the *Details of the RCA Tool Selection Approach* that used the contingency principle demonstrated that such principle can offer the flexibility the teams need to perform at the maximum level according to the needs of each problem.

The varieties of potential problems need to be identified and explained. This explanation would help to make clear what tool is the most appropriate to use.

It is also recommended to develop a lessons learned tool. This tool should help development engineers and test engineers during the project realization phase to share knowledge and inquire about problems and solutions of previous experiences. Because of the scope of this research, this is the only recommendation that is not going to be included on the design of the solution offered in this project.

IV – Design of Incorporation of Best Practices in Philips Healthcare

In this chapter, the recommendations of the confrontation results presented in the previous section will be developed. This section shall inform about the design of the approach for RCA tool selection, explaining how it acquired its final shape.

The concept of root cause analysis as well as different topics surrounding it, as the *RCA Triggers* are developed on section *Root Cause Analysis*.

The section *Design of the RCA Tool Selection Approach Based on the DI-RF Cycle* mixes the already explained concepts of the *DI-RF Cycle* and the approach for tool selection. It describes as well the most important activities that need to be developed.

On section *Contingency Approach Design* the characteristics of the contingency principle attached to the RCA tool selection are explained.

Finally, section *Lessons Learned* promotes the utilization of an organizational wide tool for sharing knowledge.

Section *Design of the Contingency Approach for RCA Tool Selection* develops on the final aspects to complete the design of the outcomes of this research.

4.1 Root Cause Analysis

The objective of this kind of analysis is to find the factors to be solved no only to correct the product defect, but also to avoid that it happens again.

An RCA is tool that can be considered expensive in the sense of effort (Mays, 1990) and time consumed (Grady, 1996); therefore it should be applied only to those defects worthy of such investment. To guide this decision, on section *RCA Triggers* explains the reasons for which an RCA should be performed in the host organization.

4.1.1 RCA Triggers

The decision to make an RCA implies a great effort that can be considered expensive in resources and time by the organization. Nevertheless, if used in the correct problems, The RCA can truly save much time and effort by dedicating one team to analyze a specific effect.

Even though the previous statement is true, it is also important to filter and select only the defects that need an RCA. To do an RCA for 100% of the defects will slow down the solution implementation and most likely reduce the quality of the products and processes, together with a series of inconvenient situations as can be fully booked RCA teams, excessive time expanded on RCA and therefore not enough time invested on primary position requirements, etc.

Because of this, the RCA Triggers are very important. The RCA Triggers are the guides that help the practitioners to answer the question "Is this problem worthy of investing an RCA on it?"

The following are the RCA Triggers defined for the specific organization that hosted the project, it does include some industry specific aspects, but most likely, this RCA Triggers are easy to adapt to different organizations among the different industries.

Safety Issues

Any defect that causes a potential harm to the user or patient shall be classified as a *Safety Issue*. These defects have to be analyzed through a root cause analysis, to find out how it was originally caused.

Regulatory Requirements

For the host organization, the regulatory requirements come mainly from the FDA (Food and Drug Administration). This entity is the ruling body that regulates, certifies and allows the sales of products (as food, drugs, medical devices, etc.) into the American market. The development processes and performance of such products must comply with the FDA Requirements.[3]

The FDA requires to analyze and document specific sort of problems found in the product before it is released to the market.

Group Judgment

There are defects that even though are not safety issues nor required to have follow-up by regulatory requirements, present a big threat under the judgment of a group of experts. Therefore, having the motivation to avoid such problem to grow and become one of the previously mentioned kinds of defects, it will trigger the creation of an RCA. This way it will find its source and solve it at the earliest phase possible.

Trending

It is possible that most of the defects managed have a common characteristic. It is possible as well that given that such problems are not in the previously mentioned triggers, never get to be analyzed to find the root cause. It is a waste of effort solve every time the same problem if there is no effort to try to solve the source. This is the main reason to have Trending taken into account as an RCA Trigger.

The goal is to create an RCA of the defect that has most iteration or repetitions on the development process. The purpose would be to improve the process and therefore eliminate the defect from its source.

[3] http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm

Customer Feedback

This category can be seen as the extension of the voice of the customer thus it can be heard. The defects or problems found in the field by the customer can be analyzed with the same tool as the defects found on the development process.

The reason for not setting this trigger more above on the rank is because the main purpose in the scope of this research project is to solve the problems before the product reaches the customer. Nevertheless, the customer feedback can be useful for current and future projects.

Product/Process Improvement Project

The last trigger has the purpose of improve the quality of the product. It is divided in two categories; reliability and performance.

Reliability

The idea is to analyze the defects or lack of reliability of some aspect of the equipment at system integration phase. The ultimate purpose is to understand the reasons that decline the reliability and solve it.

This would help to increase reliability of parallel and future products as well.

Performance

The idea is to analyze the defects that decline the performance of some aspect of the equipment at system integration phase. The ultimate purpose is to understand why the poor performance was created and solve it to enhance the performance of that specific product as well as parallel and future ones.

The last three categories are defined to give a guideline of the potential usage of the approach by including these triggers. It is important to mention that given the scope of this project is limited to the analysis of the defects found during the *Project Realization* phase, before the launch of the product to the market; these categories (Trending, Customer Feedback and Product/Process Improvement Project) are left for further research.

4.2 Design of the RCA Tool Selection Approach Based on the DI-RF Cycle

The RCA tool selection approach has a place on the development of the DI-RF cycle *Figure 10* offers an illustration which purpose is to help the reader to understand relationship of the approach inside the model.

As in the *DI- RF cycle on the Product Development Process* shown on section *Synthesis of the Best Practices Towards Applicability*, in *Figure 10 Approach embedded on DI-RF Cycle* can be found the production process in which the defects are introduced (DI). This action is considered to happen spontaneously, since there is the assumption that nobody provokes intentional defects on the product.

After this section, the defects are detected (DD). As mentioned on section *Introduction to the Problem* the scope of this project is limited to the defects detected before the *RfLD (Release for Limited Delivery),* this limits the scope to defects found before and during the *test validation* stage.

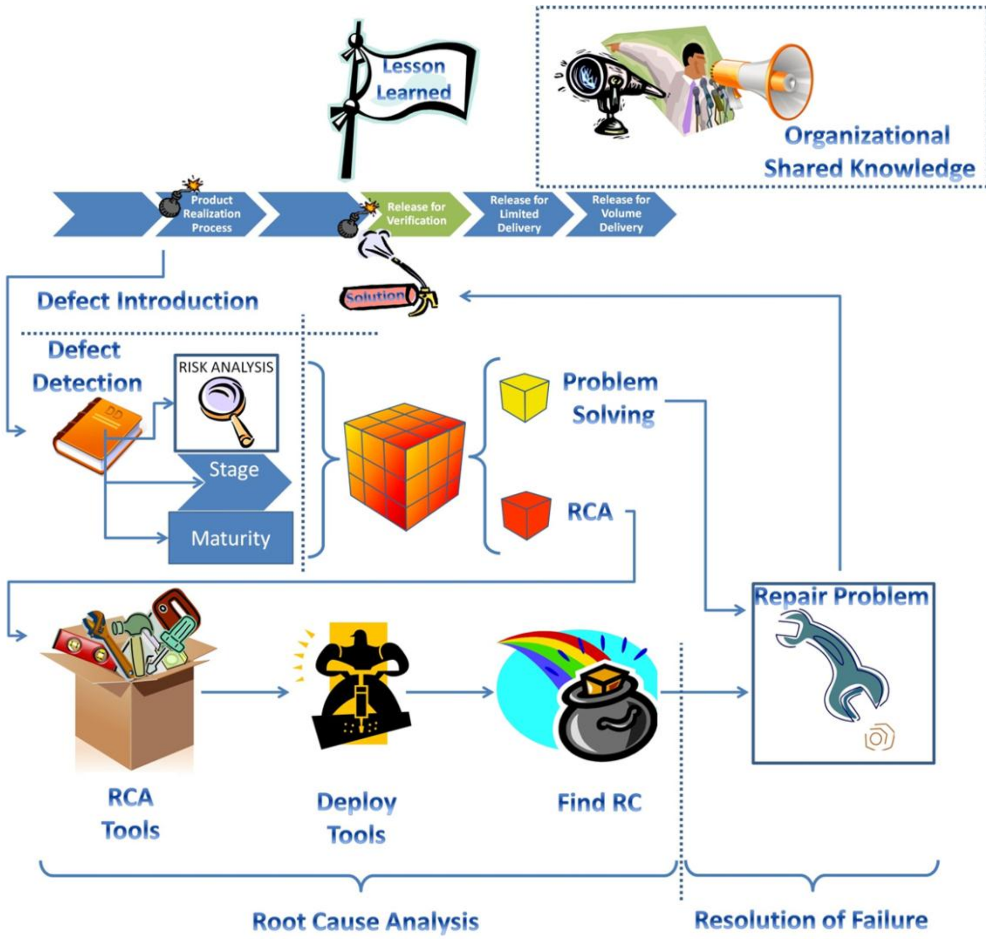

Figure 10 Approach embedded on DI-RF Cycle

Once detected, the defects can be categorized by means of a *risk analysis*, also identifying other factors that might give some differentiation to the problem characteristics. The risk analysis is the key activity done during the defect detection section.

The root cause analysis section is only triggered if the risk analysis of the DD section determined it; for this decision, the specific triggers are introduced in section *RCA Triggers*. If any of the triggers goes off, the RCA tool selection approach is initiated depending on the categorization carried by the defect.

When the RCA is triggered, and the root cause of a problem is found, this root cause is informed to the defect owner, which is in charge of taking actions, therefore arriving at the Repair Problem (RF) section. Otherwise, it is assumed that the defect does not need a further investigation, but only to be repaired. This is the Resolution of failure section (RF) to which is possible to arrive through the RCA path as well.

The solution is illustrated in the diagram by the fire extinguisher. It represents the extinguishing of the flame (the problem). Every time this happens, a sign should be indicated, as shown with the Lessons Learned flag. The organizational shared knowledge is only achieved once the organization has implemented a program in which the experiences of peers can be effectively communicated to the relevant members in the rest of the organization, to avoid or repair similar problems.

4.3 Contingency Approach Design

As mentioned in the *Details of the RCA Tool Selection Approach* section, the contingency principle, the idea of being able to use different kind of resources already specified to given scenarios taking into account different variables, is a fundamental idea for the proposed approach.

In this case, three dimensions were found to be relevant to influence the differences on the problems. It is needed to face such problems with a variety of tools that cover specific characteristics, thus enhancing the performance of the tools when using them to a certain type of problem.

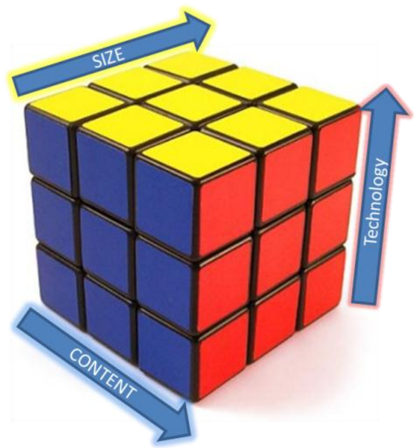

Figure 11 Illustration of Approach contingency concept

The dimensions chosen for this specific project are the following:

- Size
- Content
- Technology

It is important to mention that this dimensions where chosen after a thoroughly analysis that is in line with the methodology described for this project, more about the logic supporting the selection of this specific dimensions can be found on the section *Definition of Project Types inside the Organization*. Thus, when trying to apply the general idea of this approach for a different organization, it is possible that these dimensions vary depending on the factors that influence more on the diversity of problems.

4.4 Lessons Learned

By having interviews and insights from the stakeholder of the process, the lessons learned tool is regarded as a needed way to promote the communication among the organization and create common knowledge valuable for parallel and future projects. The lessons learned help the practitioners to distinguish throughout the time which tools were successful and which not while using them to solve certain kind of problems of certain type of projects.

The organization requires preserving the knowledge of its members. This can be achieved by historical records from the experience of the members while performing their task in a position within the organization. It is well known that in spite of that concrete people accomplish concrete tasks, knowledge abstraction, from people experiences, is done by working at each organization position. Organization knowledge and experiences shall be integrated from individual knowledge and experiences (Alvarado, Romero-Salcedo, & Sheremetov, 2004).

For this reason it is important to promote a tool that captures the lessons learned from the individuals throughout the organization. This tool not only should save these experiences, should also be capable of sharing information (manually or automatically) in a clever way. This means that persons that are involved on a similar project or have a similar problem are flagged to be aware of the existence of such solution already developed in the organization. Moreover, to solidify this tool, it should be encouraged the utilization of such tool as an input for activities of the early phases of the product development process.

This section served as an introduction to the lessons learned principle. The scope of the present research does not include a further development of this topic. It is encouraged to give follow up to this aspect with further research.

4.5 Relationships, Stakeholders and Activities Needed for the Implementation of the Contingency Approach

Considering work discussions, and organizational analysis, the following requirements for the implementation of the contingency approach were found.

1. Defect handling procedure (Environment where the information flow will be performed)
2. Process owner (Stakeholder responsible to produce according to specs)
3. Product responsible (Stakeholder responsible to establish product specs and assure the product complies with them)
4. Production (activity)
5. Tester (Stakeholder responsible to audit that the product complies with its requirements)
6. Inspection activity (activity)
7. Product Test Information (activity)
8. Inspection decision (activity)
9. Approval entity (Stakeholder that supports or rejects Tester decision when failure is reported)
10. Investigation approval (activity)
11. Inter functional team (Set of Stakeholders that are involved in the investigation)
12. Defect Analysis (activity)
13. Root Cause Analysis (activity)

14. Problem Owner (Stakeholder in charge of correcting the mistake or eliminating the root cause)

As an initial condition that has to do with the concrete PDP, the process conditions and the product specifications need to be established by the Process Owner and the Product Responsible respectively. These conditions allow the product elaboration.

After this activity, the tester role appears by testing the product. For the defect management process purposes, the tester creates the product test information. Two different outcomes can follow such activity.

1) Send decision of no failure; for which there was not found any defect to be handled, therefore the process is ended
2) Send decision of failure

If the decision of failure is recorded, the approval entity shall inspect the decision of failure presented by the tester.

For the defect management process purposes, the approval entity has three paths.

1) Reject the failure, for which the Approval entity has to send a Rejection Inform to the tester, and in parallel, a decision of no Failure to the Product Responsible and therefore ending the process
2) If the approval entity agrees with the defect, it should decide whether it is required to order an RCA.
    a) If it is not needed, the decision of defect analysis is sent to the analyst, whom does a defect analysis and send the defect information to the problem owner.
    b) If the RCA is indeed needed, the approval entity sends a decision of RCA session. This session is performed by the Inter functional team. The conclusion of the RCA session should include the root cause of the problem and the logic of how the team arrived to such conclusion. This Defect Information is sent to the Problem Owner.

For the purposes of the defect management process, only the stakeholder "Problem Owner" was introduced, but the concrete person might as well have the process owner, product responsible, or any other role.

After having understood the relationships of the activities and stakeholders in the defect handling system, the *Figure 12* is shown. This process diagram includes 5 columns that represent the performers of the activities, which are aligned according to the responsible on performing it. On the left margin, it is explicitly shown which segment of the DI-RF cycle does each activity should be performed.

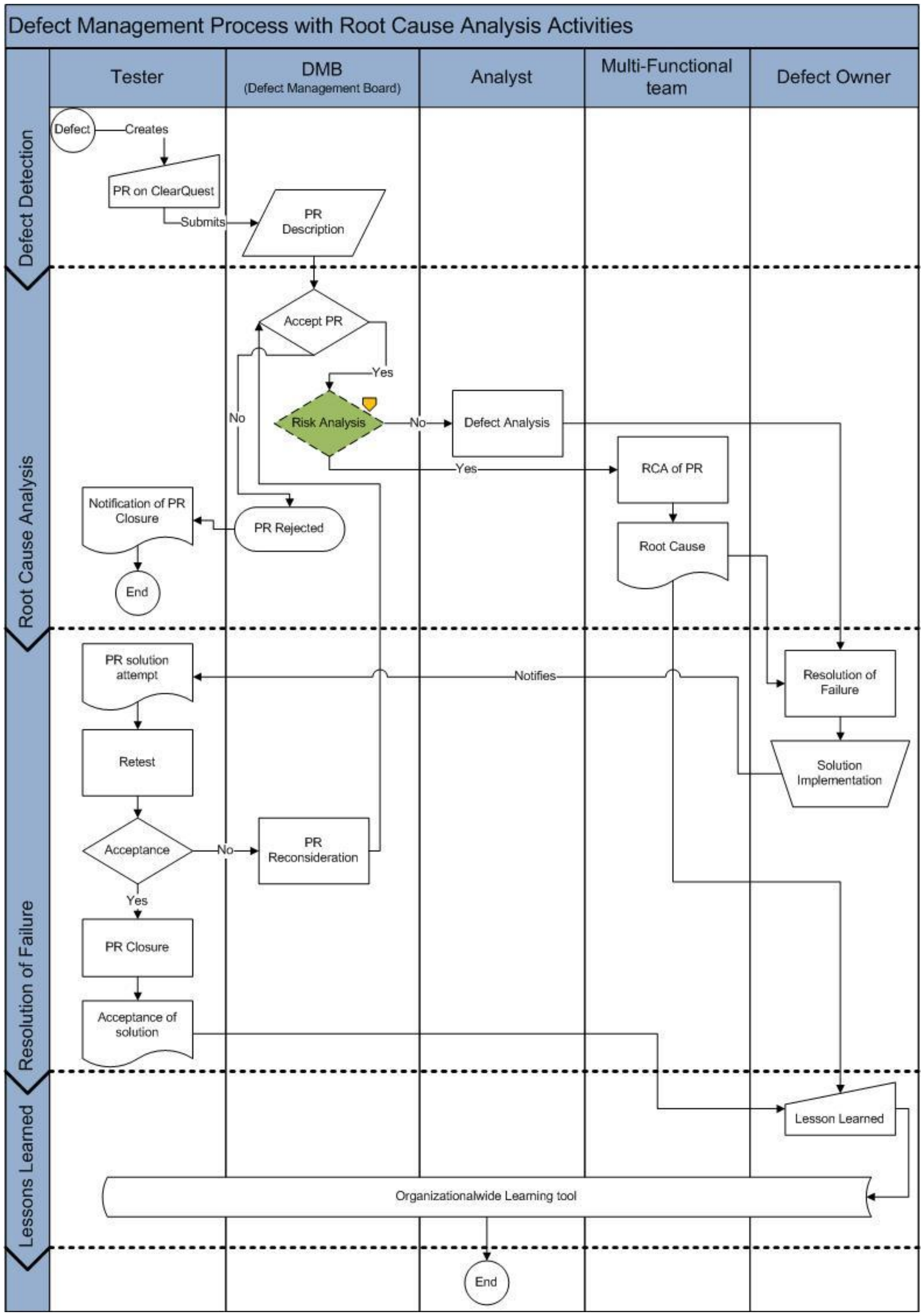

Figure 12 Proposed Defect Management Process

Figure 13 Risk Analysis Sub-process represents a section of the proposed process that was decided to expand. After a validation interview with practitioners, it was concluded that the decision of risk analysis, which selects whether or not to perform the RCA should be converted in a sub-process in which first a risk assessment decided if an issue could fit in the RCA triggers (see section *RCA Triggers*) or not. After this decision, the problem should be categorized anyway. It was possible to include this upgrade without the need of modifying the fundamental idea of the proposed defect management process since it did not changed the flow of the process.

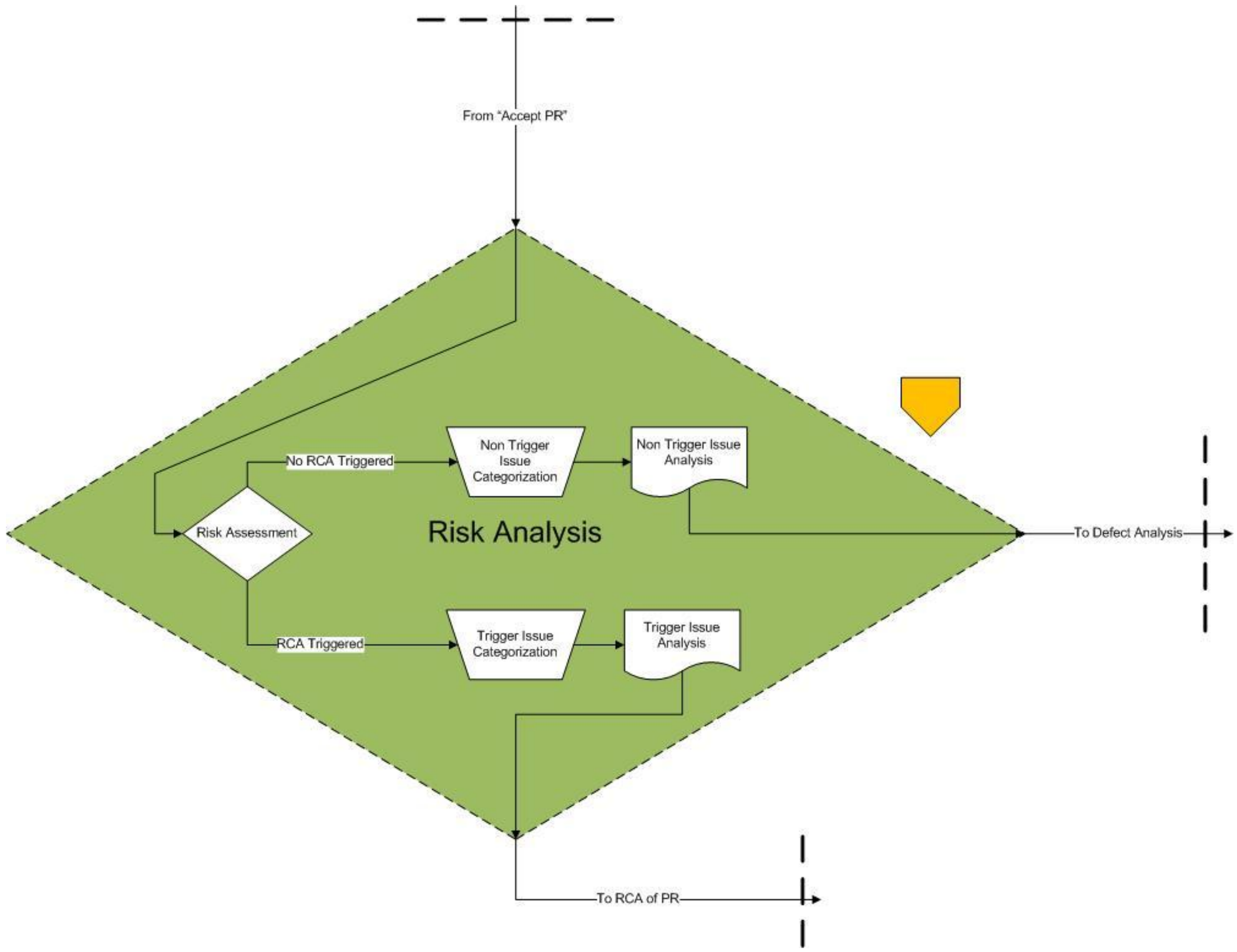

Figure 13 Risk Analysis Sub-process

For the development of the new process, the methodological process was followed. It was necessary to point out the differences between the approach needs and the current process in the organization. Then it was necessary to set the requirements to fulfill the needs of both sides. At the end it was needed to set trials and design draft processes. In this trials it was analyzed whether or not the new process complies with all the requirements.

A glossary of the symbols meaning can be found on *Appendix 1: Glossary of Process Diagram Symbols*.

4.6 Design of the Contingency Approach for RCA Tool Selection

The contingency principle of being able to use different kind of resources, given different situations, is reflected in the approach by three actions:

1. Definition of Project Categories

2. Characteristics of RCA Tools
3. Specify links between tools and certain project categories

As stated by Doggett, each analysis tool has distinguished characteristics that can potentially affect group output; a reliable decision making requires that managers have an operational knowledge of root cause analysis tools, their process and their likely outcomes (Doggett, 2005).

The purpose of this section is to elaborate on the previously mentioned actions of the projects and the tools.

In accordance to the described methodology, a research was done to be able to categorize the kind of projects in the Software-intensive Industry, and afterwards it was confronted with the current reality at the organization. For this, a Table is shown with the logic and explanation of the *Project Categorization*.

Afterwards and regarding the tools, once the characteristics are explained, a comparison matrix will illustrate at what degree each tool fulfills each characteristic.

It will be developed as well a matrix that helps to link the categories of the projects with the RCA tools, helping to decide which tool is more appropriate to be used on specific situations.

4.6.1 Definition of Project Types inside the Organization

The variety of projects among the Software-intensive products industry can be quite broad, therefore it was decided to scope the application of this contingency principle to the organization hosting this project.

For learning about the categories of the projects developed in the MRI Division of Philips Healthcare in Best, The Netherlands, an interview was arranged with a project group leader[4] where this was the central topic. It is important to mention that there is no formal categorization already distinct in the organization; therefore a brainstorm was needed to define the categories.

According to the analysis of the diversity of projects, the following categories were stated.

- Content: it can be specified as a *Hardware*, *Software*, or *Hardware-and-Software* development, for the purpose of this research it will take into account two extremes as *Software* (SW) or *Hardware* (HW)[5]. This decision can be made because specific problems that have an interaction with both parts could be treated as the one that requires more attention to detail; therefore those could be treated as an SW content issue.
- Size: Depending on the standardization of sizes, the organization can measure it as *Large* or *Small*. This measurement is inherent to the scope of the final product expected to be created by the organization.

[4] Interview with Thijs Winter on June 19, 2012

[5] After validation meeting, it was established that for one special case it was needed to combine HW+SW for the fit with the host organization. This can be seen in *Table 4 Different Type of Projects among the Software-Intensive organization*

- Technology Innovation (Can also be related as *Risk*): it can be qualified as *Revolution* (High technology innovation) or *Evolution* (Low technology innovation). Normally a 'Revolution' will contain a *High* risk and an 'Evolution' a rather *Low* risk.
- Effort: It refers to the amount of resources involved to the project. Some measures that can be taken into account are *people assigned to the project*, *Full Time Equivalent (FTE)*, or *Total monetary amount invested in the project*.
- Lead time: Amount of time expected to complete the project, can be large or short lead time (Sometimes regarded more as a product of the decisions taken for each project, than an intrinsic category)

As a manner of explanation, it was also defined that the categories of projects are somehow tradeoffs among one another. This explanation resembles a Cartesian plane in which the increase of a category placed in one end of one axis would cause the reduction of the category placed on the other extreme. It relates to the explanation given by (Reijers & Liman Mansar, 2005) for what they called 'The devils quadrangle', which uses the dimensions distinguished by Brand and Van der Kolk in relation to the effects of redesign measures: time, cost, quality and flexibility.

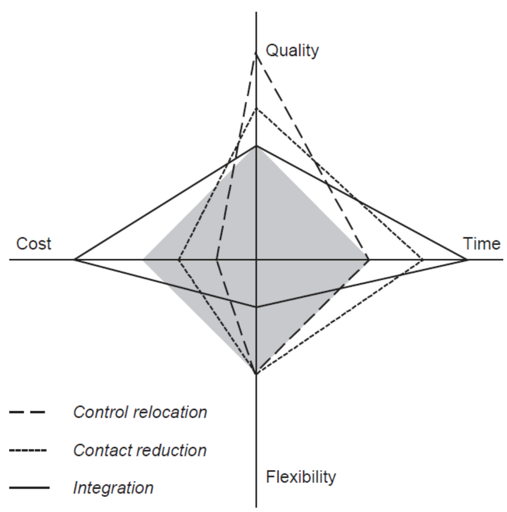

Figure 14 Example of "The Devil's Quadrangle" (Reijers & Liman Mansar, 2005)

Taking 'The Devil's Quadrangle' as fundament for the categorization, considering the Lead-time category of a project as a result that can be modified depending to the value assigned to another characteristic, rather than an intrinsic characteristic, and joining the category 'Effort' to the category 'Size', given the similar measuring systems; it can be claimed that each project has a set of three intrinsic characteristics to define them. Therefore these characteristics, which can have a set of two extreme values, offer a variety of eight different combinations (sort of projects) Nevertheless, inside the development process of the organization, only six out of the eight project types where recognized as shown in *Table 4*.

Such categories can be assorted following the *Project Categories and Degree of Risk* theory of (Cash, McFarlan, & McKenney, 1988)(pp.164).

Table 4 Different Type of Projects among the Software-Intensive organization

Project Type	Characteristic	Description	Example
I	Content	HW	ROHS
	Technology	Low	
	Size	Large	
II	Content	HW	Body Coil Deluxe Board
	Technology	Low	
	Size	Small	
III	Content	HW+SW	Obelix
	Technology	High	
	Size	Large	
IV	Content	HW	New RXES
	Technology	High	
	Size	Small	
V	Content	SW	?
	Technology	Low	
	Size	Large	
VI	Content	SW	A Functionality
	Technology	Low	
	Size	Small	
VII	Content	SW	Himalaya, complete new SW UI
	Technology	High	
	Size	Large	
VIII	Content	SW	? = First steps in technology involvement
	Technology	High	
	Size	Small	

4.6.2 Categories of RCA Tools

Given that the organization used only two RCA tools, a research was done to provide a wider range of tools. The tools selected to be included are the Cause and Effect Diagram (CED), Matrix Diagram (MD), Five Whys (FW), Interrelationship Diagram (ID), Fault Tree Analysis (FTA) and the Current Reality Tree (CRT). Each of these tools has special characteristics, procedures and templates. All this documentation can be found at the *Appendix 8: Practical Handbook Delivered to Philips Healthcare* that contains the documentation deliverable to the host organization as a manner of manual to guide the selection of the tools and its deployment.

The root cause analysis tools were divided in three categories for which these tools are useful at the moment of their deployment. The three categories were agreed in accordance to the practice of the organization hosting the project in order to cover its internal needs.

Table 5 Degree of fitness between RCA Tools and Categories

	RCA Tool	Data Driven	Oversight	Multiple Situations
1	CED	0	2	0
2	Matrix Diagram	2	1	0
3	Five Whys	0	2	2
4	ID	2	1	0
5	Fault Tree Analysis	2	2	2
6	CRT	2	2	2

It is important to mention that even though the purpose to select this categories is to align given tools to each category, it is not neglected that certain tools might fit in more than one category at some degree, therefore, the categorization does not imply that the tool only responds to that category, but that is the most representative, as can be seen on the table above, where the degree of belonging was qualified from 0 to 2, (0= does not belong, 1=belongs at some degree, 2=Belongs completely).

To make this categorization easier to understand, a graphic underneath explains the distribution of each tool according to this categorization method.

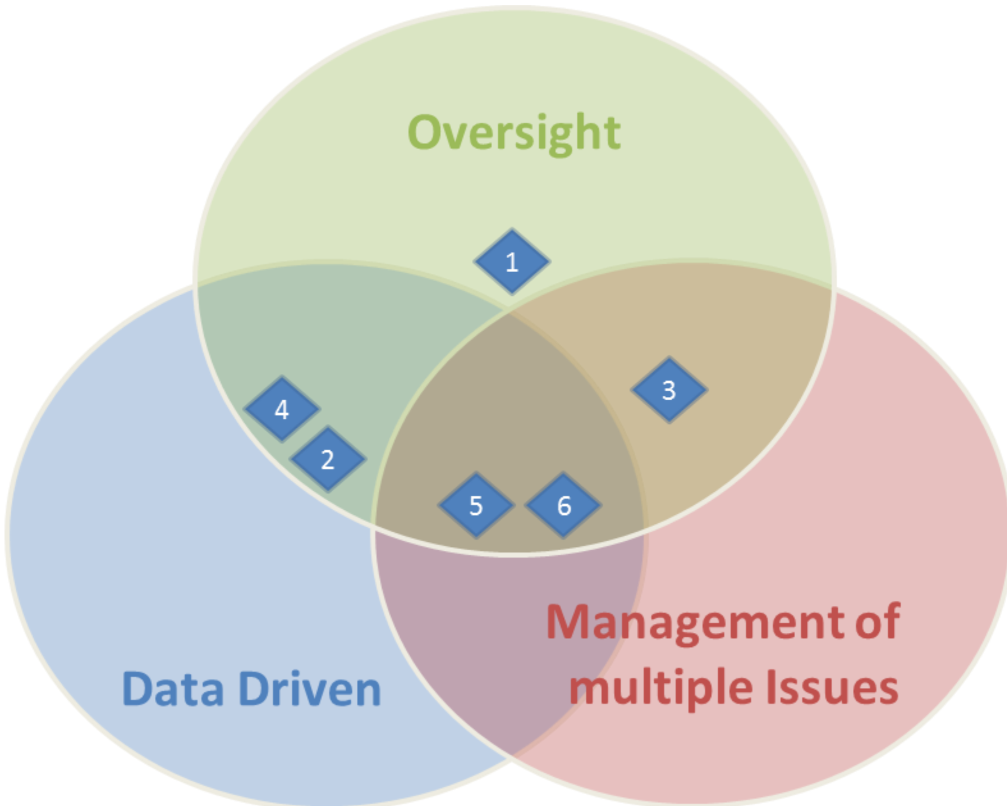

Figure 15 Distribution of the RCA Tools among Categories

4.6.3 Specific links between tools and specific project categories

From this categorization, a double recommendation can be drawn. The first one is based on best practice guidelines. The recommendations that are going to be explained are intended also to grow in number by the increased experience of the organization.

The proposed recommendations are:

1. For project defect analysis that need to be data driven, the tools of Cause-and-Effect Diagram and the Five Whys should not be selected

2. For project defect analysis that faces multiple issues simultaneously, the Cause-and-Effect Diagram, Matrix Diagram and Interrelationship Diagram should not be selected

3. For project defect analysis that need to be data driven and faces multiple issues and problems simultaneously, the Cause-and-Effect Diagram, Matrix Diagram, Interrelationship Diagram and the Five whys tools should not be selected

4. For project defect analysis with data driven and oversight, the Cause-and-Effect Diagram and the Five Whys should not be selected

5. For project defect analysis with oversight and multiple issues simultaneously, the Cause-and-Effect Diagram, Matrix Diagram and Interrelationship Diagram should not be selected

6. If the purpose is to obtain oversight from a project defect analysis, all the tools are available to be selected, but it is encouraged to use the Cause-and-Effect Diagram

As second recommendation, the suggested categories of tools prone to enhance the result of the RCA are proposed according the type of project in which it is working.

Table 6 Category selection according to project types defined

Project Type	Data	Oversight	Multiple Issues
I			x
II		x	
III	x		x
IV	x		
VI	x	x	
VII	x		x

Of course the final decision of the tool to be used remains on the group team that is going to work with it and must be having into consideration the time needed to complete the task and the level of knowledge of the tool to be used.

To find more about the logic grounding the degree of fitness between RCA tools and tool categories, and the category selection according to project types defined tables please refer to the *Appendix 6: Logic grounding the Degree of fitness between RCA Tools and Tool Categories* and *Appendix 7: Logic grounding the Category selection according to project types defined.*

V - Validation

The final chapter is dedicated to the validation of the outcome of the research. Because of the scope of the project, it was not intended to implement the results of the research in the organization. Therefore, to validate the success or failure of the approach proposed, it was decided to test the feasibility of the process and inquire the stakeholders of the organization about the potential incorporation of the work developed to their daily activities. This was done in two validation conducts.

The first validation was done with an RCA Session; the purpose of this session was twofold. First it was desired to observe the feasibility of the Defect Handling Process proposed with the practitioners. Second, it was to observe the reaction of an RCA Team to the introduction of a new RCA Tool.

The second validation was done in a manner of interviews, in which the completed outcomes of the research were explained to the stakeholders and the purpose for this interviews was mainly to investigate the usefulness of the contingency principle for the approach developed.

5.1 Validation Sessions

Two kind of validation sessions were arranged in the host organization. The first one was denominated 'RCA Pilot Session' and the second one was a 'Project Validation Interview'.

5.1.1 Design of RCA Pilot Session

Once the process is designed, the implementation stage is achieved with the *Validation Pilot Trial*. For this matters, different Problem Reports (PR's) selected from a specific project shall run through the designed process, keeping track and making use of the documents designed for each phase of the approach. The ultimate goal was to prove that the feasibility and validity of the process. The redesigned process is closely integrated to the current processes of the organization and that offers the solution required for the regulatory aspects of the defect management process.

Since the PR's are already created and is possible to run a simulation by filling the forms needed, one special part of the validation is the introduction of the multifunctional team to perform the RCA. For these matters it was negotiated with the responsible stakeholders to perform a session to introduce and evaluate an actual RCA session with different PR's.

The intention is to show to the stakeholders the purpose of these sessions, how should be managed and what is the expected outcome. Moreover, completing the session will validate the whole process redesigned.

The explanation of the purpose and intentions of these sessions where explained to the Testers Managers. It was explained to them the objective of the project and highlighted the need for this validation phase. Therefore it was asked for their support and approval for the use of time of experts from their teams. Invitation for this session can be found on *Appendix 4: Explanation of the RCA Validation Session sent to Test Managers*.

These are the steps for the development of the sessions:

1. Involve Test Engineers managerial level and ask for support and resources
2. Require information about which project is more feasible to analyze and which people is more keen to help for the purpose
3. Explain that the final purpose of the pilot is to validate the process, not to evaluate the outcome of the RCA session.
4. Introduce the RCA Tool to be used
5. Facilitate the session
6. Document outcomes of the session

The methodology, evaluations and suggestions of this session can be found on *Appendix 5: Outcome of RCA Validation Session.*

5.1.2 Validation Conclusions of RCA Pilot Session

The validation phase was developed by having the observation of the proposed procedure on 7 different real life problems from the organization, since it involved real life problems with the adequate stakeholders, this validation can be catalogued as a strong validation in a simulation phase. After the elaboration of this validation process, four conclusions can be draw.

1. The procedure proposed had to be fine-tuned to best illustrate the procedures followed at Philips, having into consideration that such modifications would not compromise the performance of the defect management process proposed (*Figure 13*).
2. After analyzing the selected defects throughout the proposed procedure, there was no fundamental flaw on the logic, or block on the practice that would prevent the process to work.
3. The causes found after the RCA Session deployed for the 7 problems demonstrated a deeper level of understanding and contribution to solve the problem that the ones reported on the Philips quality system “Clearquest”.
4. Acknowledging the previously mentioned evaluation given by the participants of the session, it can be concluded that the procedure helps to arise structure and focus to the sessions of RCA.

5.2.1 Project Validation Interview

This project validation interview was held with 4 key stakeholders in the process (System Test Engineer, Software Development Engineer Coordinator, Integration Architect and Technology Integration Engineer).

The method followed for this interview was to explain in a stepwise manner the outcomes of the research as the proposed defect management process, the risk analysis sub process, the explanation of the different type of projects among the Software-Intensive organization, the degree of fitness between RCA tools and categories, the categorization of RCA tools and finally the category selection according to project types defined. For each one of these sections it was asked to analyze and declare whether they recognize the feasibility and relevance of the project outcomes.

For the topic of introducing new and unfamiliar tools to the RCA practice, it was asked in their point of view, what would be the best way to introduce successful meetings that would follow the RCA tools proposed.

At the end, it was asked in their point of view, what would be the biggest obstacle when trying to set these results to the practices.

5.2.2 Results of the Project Validation Interview

Nevertheless this was just a soft validation since it mostly asked for certification, it was very compelling to receive a very good respond by the stakeholders interviewed.

All of them answered that there is complete feasibility for the results to fit with the organization processes and way of work. Moreover, almost all of them mentioned that it was a very good outcome; the idea was complete and functional. It was even forecasted that if implemented, the organization would be more efficient than currently.

Special mention was given to the multifunctional team specified in the defect management process. It was positive in their sight that the process definition included the RCA, because in that way, the system would be ready for this type of activity.

It was strongly suggested by the interviewees to avoid the usage of RCA for a big number of defects, but rather limit the amount of problems passing by this stage. It was also mentioned that it is needed to implement a feedback loop of the problem solutions in the mode of lessons learned.

Regarding the best way to introduce successful meetings that would follow the RCA tools proposed it was mentioned by most of them that it was important to train intensively to 1 or 2 facilitators that dominate the new tools, and to have them as facilitators of the RCA Sessions. Also an important point made was that it is needed to create awareness of the new tools among the employees that would eventually be using it.

In fact, the biggest concern to be able to put in practice the approach was related to the capability of the organization to implement it and not to the content of it at all. One of the reasons given for concerns of the implementation was that it is hard to introduce new tools, and that people might get reluctant to use RCA tools different to which they already know.

VI – Conclusions and Further Research

6.1 Conclusions

The conclusions of this research project are the following:

The root cause analysis is a powerful tool, which being used in a structured manner, can be quite useful for process improvement efforts.

Considering the *DI - RF cycle*, the RCA tool selection approach works as a theory-based guide to give structure and order to the practice. It is generic enough to be taken by any company of any branch of the industry and compare it to their current situation to diagnose a needed change of direction for organizational improvement.

The defect management process that was redesigned worked as a two steps improvement on the organization's current process. First, it helps to introduce the two important decision points for establishing the need of an RCA. If RCA is needed, such process deploys the selection of a tool. Moreover, the introduction of the multifunctional team as a stakeholder inside the definition of the process is fond of the practitioners, who accept the need and benefits of analyzing the problems in this manner. Another improvement from the analytic point of view of the model is that it is no longer possible to set the defect in a state without further activities.

The specific RCA tool selection allows to enrich the experience of the activity by helping practitioners to use from the beginning a tool that will enhance the performance and result of the analysis, regardless of their previous experience with this kind of techniques.

This project has achieved to develop a stepwise structure in which the relevant processes, stakeholders and activities of an organization are confronted to the best practices of the literature and are modified for enhancing the result of the RCA done.

The contingency principle has demonstrated through the validation to be a common sense idea, which nonetheless is often overlooked. The inclusion of the contingency approach for RCA Tool selection offers to the defect analysts the maneuverability needed to have meaningful, productive RCA sessions. These sessions are often adaptable to the environment of the project and the defect itself as it can be decided the most appropriate tool to perform it based in different aspects (e.g. the project types, the defects essence, and the availability of people).

6.2 Further Research

Further research can be developed to clarify the interaction of the Preventive Approach Tools (e.g. FMEA's) in the Product Development Process and the DI-RF cycle.

The *RCA Triggers* trending, customer feedback and product or process Improvement project are also material for further study aiming to extend the current research to include the defects found after the Release for Limited Delivery.

The Trending in particular offers several branches of extension of the study. One of this branches that was suggested but not developed in the current research is the triggering of an RCA for the root causes that had been found in reiterative occasions.

The aspect of *Lessons Learned* is regarded as a relevant issue to the organization, further research in this topic is encouraged.

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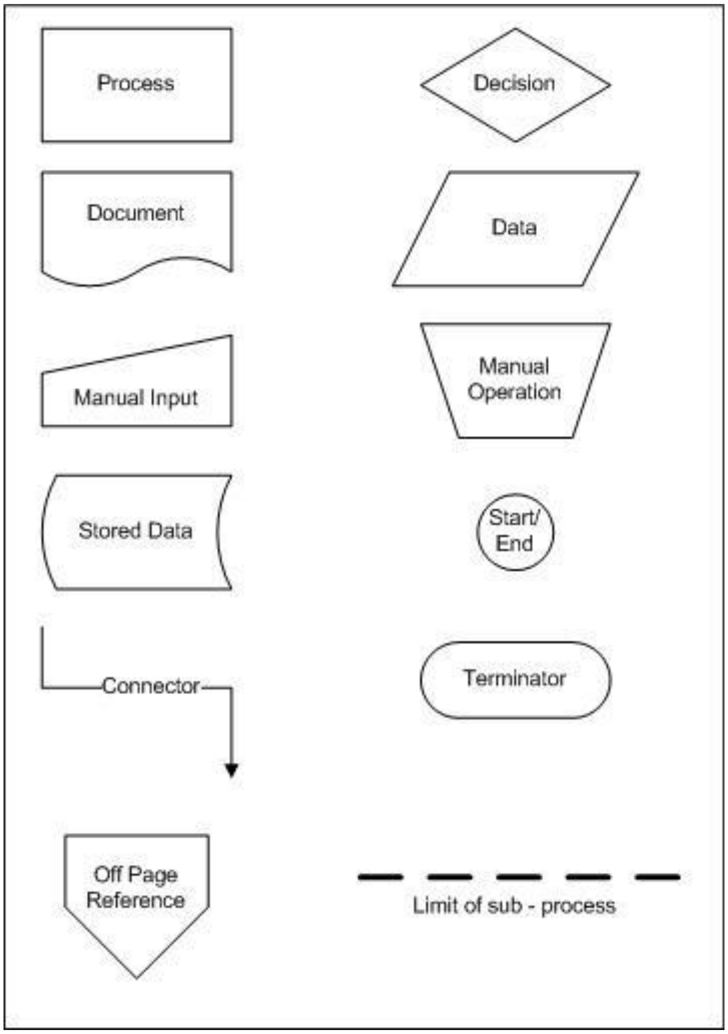
VII - Appendixes

Appendix 1: Glossary of Process Diagram Symbols



Appendix 2: Minutes with stakeholders

<table>
<tr><th colspan="3">Introduction with System Verification Procedures</th></tr>
<tr><td>2.21.2012</td><td>15:30</td><td>QR-1155 (Paul’s office)</td></tr>
<tr><td>Meeting called by</td><td colspan="2">Jan van Moll</td></tr>
<tr><td>Type of meeting</td><td colspan="2">Introductory to Root Cause Analysis Project and interaction with System Verification</td></tr>
<tr><td>Attendees</td><td colspan="2">Jan van Moll (JvM), Paul Derckx (PD), Daniel Vallejo (DV)</td></tr>
<tr><th colspan="3">Introduction of the project of Root Cause Analysis</th></tr>
<tr><td>5 min</td><td colspan="2">Jan van Moll</td></tr>
<tr><td>Discussion</td><td colspan="2">Introduction of the project of Root Cause Analysis to Paul. It has been discussed that the interaction of</td></tr>
<tr><td colspan="3">the project will mainly have as principal stakeholder Paul’s group (System Test).</td></tr>
<tr><th colspan="3">Explanation of the project of Root Cause Analysis</th></tr>
<tr><td>15 min</td><td colspan="2">Daniel Vallejo</td></tr>
<tr><td>Discussion</td><td colspan="2">What is the main idea of the project? What aspects should be covered?</td></tr>
<tr><td colspan="3">Explanation of the Framework structure, the ideas to analyze the different stages and inclusion of Risk Analysis to evaluate the</td></tr>
<tr><td colspan="3">Severity of the problems to define the RCA Tool to be used.</td></tr>
<tr><td>Conclusions</td><td colspan="2">-The Framework should help to have a structured way to develop RCA. Moreover should be general enough</td></tr>
<tr><td colspan="3">In order to be able to re-apply it on the bottom procedures of the Subsystem and Components “V-shaped” lifecycle.</td></tr>
<tr><td colspan="3">-It is intended to create a relationship between the problems solved (lessons learned) to use them as inputs on parallel projects organizational wise.</td></tr>
<tr><td>Action Items</td><td>Person Responsible</td><td>Deadline</td></tr>
<tr><td>Be aware of the processes followed by the Sys ToR group</td><td>DV</td><td>28/2/2012</td></tr>
<tr><td>Define inputs needed from Sys ToR group to the Framework</td><td>DV</td><td>28/2/2012</td></tr>
<tr><th colspan="3">Explanation of the System Test (ST) Process</th></tr>
<tr><td>60 min</td><td colspan="2">Paul Derckx</td></tr>
<tr><td>Discussion</td><td colspan="2">Explanation of the processes followed by the System Test group.</td></tr>
<tr><td>Conclusions</td><td colspan="2">-It is important to challenge Requirements in order to improve the quality of the product.</td></tr>
<tr><td colspan="3">-There are 6 to 7 system level requirements specifications for system verification.</td></tr>
<tr><td colspan="3">-The RFV is an important milestone. There a lot of actions take place. End of Development (EOD) so the changes are frozen. The Release is launched, sets the border between Engineering Issues (Lightweight corrected n the main stream) or Product Defects (Very Strict, Formal defects corrected on the released version).</td></tr>
<tr><td colspan="3">-After RVF the Verification and Validation of the system is done over a released stream.</td></tr>
<tr><td colspan="3">-The time between RVF and EV(End of Validation) is around 2 to 3 months</td></tr>
<tr><td colspan="3">-The ST has two tasks on the PLC; Challenge the requirements when developed, and at the validation stage, show that each Requirement has a validation test.</td></tr>
<tr><td colspan="3">-In the system level a modular approach for Requirements testing is being implemented. In the bottom levels the structure is still undefined</td></tr>
<tr><td colspan="3">-There is the need to establish a tool that feedbacks different releases when a problem is solved and it might be included on previous releases or even the Mainstream.</td></tr>
<tr><td colspan="3">-The way of working of the ST team is through expertise domains through the system requirement testing.</td></tr>
<tr><td colspan="3">-It is seek to have interchangeable experts</td></tr>
<tr><td colspan="3">-It is expected to have two projects per year and should not overlap. (Even though currently there are 3 projects running in parallel)</td></tr>
<tr><td colspan="3">-Douglas Blakeley’s department is in charge of the creation of the Requirements</td></tr>
<tr><td colspan="3">-A change in the requirements has to coordinate different departments efforts and resources</td></tr>
</table>

3.5.2012	11:30	QY-1036A (Harrie's office)
Meeting called by	Daniel Vallejo	
Type of meeting	Introductory to Root Cause Analysis Project and interaction with RCA Complaint Process	
Attendees	Harrie Schellekens (HS), Daniel Vallejo (DV)	
Introduction of the project of Root Cause Analysis		
5 min	Daniel Vallejo	
Discussion	Introduction of the project of Root Cause Analysis to Harrie. It has been discussed that the interaction of	
The project with the activities done by Harrie regarding RCA		
Explanation of the RCA Template		
40 min	Harrie Schellekens	
Discussion	It was discussed what is the process through which the Investigation Plan & Report Template (Philips MR Best Quality System, XJV-070019.01)	
The system for defining the Green, Amber or Red category was explained		
The fact of having always the same two tools to find the RCA was explained		
The fact that the Requirement Management could be the reason of many problems. (this should be proved by the RCA FW)		
The explanation of the differences on the word "Risk" since a given date of the previous year.		
The fact that there is no real linkage between the solutions presented to solve the complaints and its actual implementation on the product		
Conclusions	It is responsibility of one Main Investigator to give total follow up to the case and when needed, include Technical Investigators (that might also be predefined by component) to help to find the Root Cause of the problem	
The Green, Amber and Red category is given by the "Complaint Triage: initial priority setting" diagram. Then, the given priority demarks which activities have to be filled on the (Philips MR Best Quality System, XJV-070019.01, 2012). It was discussed the reason why there is a double green decision on an "If" decision.		
Because it is not expected that Technical Investigators to be familiarized with more formal RCA Tools, and are not expected to be part of an RCA so often, it was decided to always do the RCA based on the "Cause and Effect Fishbone Analysis" and having it completed with a "5 Why's? Analysis"		
After the meeting it was decided that the fact that the Requirement management could be weak is a good context information, b ut should not bias the structure of the RCA Framework intended to be developed.		
The two meaning of the word Risk are 1. Impact to the project timing, budget and resources (old one) 2. Hazards to patients and customers health or wellbeing .		
The Feedback loop for the implementation of the RCA and RF solutions to the project and to parallel, past and future projects has to be a priority since there is a lack of this kind of tool on the organization.		

<table>
<tr><th colspan="3">Introduction with RCA Complaint Process Template</th></tr>
<tr><th colspan="3">Introduction with Jasper Verduyn</th></tr>
<tr><td>3.8.2012</td><td>9:00</td><td>QR-1348</td></tr>
<tr><td>Meeting called by</td><td colspan="2">Daniel Vallejo</td></tr>
<tr><td>Type of meeting</td><td colspan="2">Introductory to Root Cause Analysis Project and interaction with RCA Complaint Process</td></tr>
<tr><td>Attendees</td><td colspan="2">Jasper Verduyn (JV), Daniel Vallejo (DV)</td></tr>
<tr><th colspan="3">Introduction of the project of Root Cause Analysis</th></tr>
<tr><td>40 min</td><td colspan="2">Daniel Vallejo</td></tr>
<tr><td>Discussion</td><td colspan="2">Introduction of the project of Root Cause Analysis to Jasper.</td></tr>
<tr><td colspan="3">Special emphasis on feedback loops and lessons learned tools. Questioning the scope of Resolution of failure meaning at the Framework</td></tr>
<tr><td colspan="3">Talk about how to measure up the effectiveness of the FW came up the idea of having it measured the amount of time that takes to implement an improvement on the projects and compare it to the time it took previous the implementation of the FW.</td></tr>
<tr><td colspan="3">On the definition of tool utilization, it is also promoted the idea of formal training to specific people so the understanding of the tools is better.</td></tr>
<tr><th colspan="3">Jasper Verduyn</th></tr>
<tr><td>15 min</td><td colspan="2">Jasper Verduyn</td></tr>
<tr><td>Discussion</td><td colspan="2">Explanation of Jasper's responsibilities with the testing of reliability and Revisions of the Defects after delivery to customers.</td></tr>
<tr><td colspan="3">Normally the process currently develop are lineal and have no feedback loop. It is good to feedback the process to understand what can be improved.</td></tr>
<tr><td colspan="3">Currently there is a Firefighter culture. (Contrary to the preventive culture looked for)</td></tr>
<tr><td colspan="3">There should be a tool to synchronize the knowledge of the organization.</td></tr>
<tr><td>Conclusions</td><td colspan="2">It is decided that the Reliability test responsibility will be the most appropriate to apply for the RCA Project in the sense that it is before the product is released.</td></tr>
<tr><td colspan="3">It is possible to create a flow of lessons learned that have input on some tools to take them into account for new projects. (D-FMEA, Design Reviews)</td></tr>
<tr><td colspan="3">The repairs of the defects might cause new problems, for that an "Effort and risk analysis" is held on the potential solution before is implemented.</td></tr>
<tr><td colspan="3">It is found that the Resolution of failure will not be inside the scope of the project itself, but will be a product of the analysis.</td></tr>
</table>

Introduction with Marianne Wiersma-Kruit		
3.13.2012	15:00	QX-2092C

Meeting called by	Daniel Vallejo
Type of meeting	Introductory to Root Cause Analysis Project and interaction with ClearQuest
Attendees	Marianne Wiersma-Kruit(MW), Daniel Vallejo (DV)
Introduction of the project of Root Cause Analysis	
5 min	Daniel Vallejo
Discussion	Introduction of the project of Root Cause Analysis to Marianne.
Special emphasis on feedback loops and lessons learned tools. Questioning the support of CleaQuest for this purpose	
Talk about what is the process of the birth of the defects on ClearQuest. How the defects are categorized.	
On the definition of tool utilization, it is also promoted the idea of formal training to specific people so the understandin g of the tools is better.	
Marianne Wiersma-Kruit	
5 min	Marianne Wiersma-Kruit
Discussion	Analysis of how ClearQuest works in the sense of resolved issues in MRI Systems.
Possibility of doing queries to find out solutions to problems	
Analysis of a potential support of ClearQuest to a Feedback loop	
Analysis of the input for defects of ClearQuest	
Conclusions	Every defect has to be filled out with the functional Area.
Most defects on CQ are not completely filled as in any Root Cause or functional area.	
The input for CQ respecting to defects are in order: -Test ; -Track wise; -Review	
The feedback loop is not really used nor supported by CQ. Currently all the defects solved are public via CQ, the problem is that most of them are not correctly filled, moreover, it depends on the responsible of parallel projects to make the queries and find related problems to its project. Not a really efficient way of letting know people what problems have been happening before, on which stages, and the reason why.	

Trending Analysis of defects		
4.2.2012	11:00	QX-2062 C (Hans Jenniskens office)

Meeting called by	Daniel Vallejo
Type of meeting	Introduction of the Trending Analysis of defects
Attendees	Karel Eerland (KE), Hans Jenniskens (HJ), Daniel Vallejo (DV)

As is situation at Philips Healthcare (MRI Systems) (Complaint handling after release)

30 min	Karel Eerland and Hans Jennskens
Discussion	Explanation of the current work of the Trending analysts.

Their input is the complaints coming from the field. KE is responsible for the complaints and HJ is responsible for the Root Cause Investigation and at some point the solutions or implementation of solution.

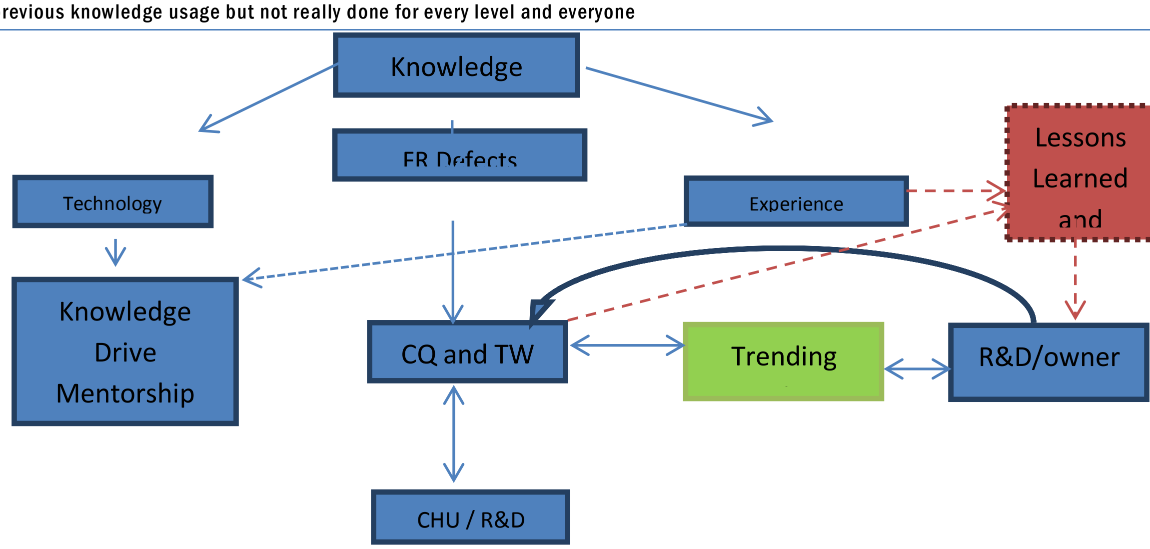
For the database analysis and possibility to find trends, every defect is coded; this allows the creation of trend reports.

These trend studies are done Quarterly. Once a Trend is detected and is wished to be solved, a CAPA (Corrective and Preventive Activity) is filled and handled via Track wise. A special team is established to give a follow up and closure to that specifi c CAPA. The CAPA cannot be closed until a specified amount of time for verification of the solution has passed. It is more regulatory oriented.

The CAPAs are based on multidisciplinary teams.

No Communication tool available to share the knowledge coming from de CAPAs.
HJ mentioned about a Project Closure in which the procedures and tips are commented in order to identify which parts of the development of the software in his previous group would be better if done differently. This can serve as a basis for future p rojects as input of best practices for the project. Those Project Closures are specified as a task of the work instruction, but is not standardized the methodology at which it is meant to be used (It is more of a personal feeling than a specification). Records of the Proje ct Closure for the Development Software Group can be found on Agile or the Central Share Drive.

MPI project do a lot of defect analysis and try to improve current projects with previous experience of knowledge. Several ar eas of previous knowledge usage but not really done for every level and everyone



No best practice or Lessons learned really implemented on Philips, It is possible to find in some SW development areas Checkl ists that specify what the engineer should not forget. Wiki is an informal work instruction that is not part of the Quality Manag ement System

Appendix 3: Questionnaire for Testing Engineers

1. What kind of problems do you look for?

2. What input do you need to do the test?

3. How do you analyze the input?

4. Do you use a structured procedure to analyze the data?

5. What do you do when finding something that does not complaint with the requirements?

6. Do reconsider the analysis?

7. When do you stop doing the test?

8. What is your output for the test?

9. Who receives your output?

10. Is the output registered in some system?

11. When re-testing, what do you run a complete new test?

Appendix 4: Explanation of the RCA Validation Session sent to Test Managers

RCA invitation

Root Cause Analysis is an activity with certain characteristics:

- Is done Jointly in a group
- Is done in a Multidisciplinary team
- Is structured and takes a specific method into account
- Is possible to achieve certain level of consensus
- Is evidence-based

Currently for some defects, there is the need to fill a Root Cause Analysis on the documents, nonetheless, currently the RCA is done unilaterally, solely opinion- or expert-based and sometimes include ideas of how to solve the problem. There is not a real representation of the multidisciplinary team that might help to point out the potential causes for a given defect and the inclusion of various viewpoints to the problem at hand.

Is because of this, that a structured methodology to apply the Root Cause Analysis to specific kind of defects has being developed.

In this occasion I invite you to participate in a session to elaborate Root Cause Analysis that covers all of its characteristics. This session is intended to improve the understanding of RCA among the MRI systems and at the same time, evaluate the feasibility of the process designed to embed this new methodology in the current Philips processes.

The main goal of this methodology is to enable the organization to grow to a level where it is able to do professional and solid RCA to eliminate existing and prevent occurrence of problems. Next to that, secondary goals are to comply with the FDA Regulations, reduce the amount of defects on the system before is ready to be delivered to the customer, and create a feedback to the organization to share the knowledge acquired. The achievement of such objectives will help to reduce effort and resources needed to solve problems of products already in the market, which are in proportion, much more expensive than when the product is still being developed.

RCA Triggers

Safety Issues

Any defect that causes a potential harm to the user or patient shall be classified as a *Safety Issue*. These defects have to be analyzed through a Root Cause Analysis, in order to find out how it was originally caused.

Moreover this is one of the defects specified by the FDA to require a documented analysis and plan of actions.

FDA Requirements

The FDA is the ruling body that certifies and allows the sales to the American market. The development and performance of our products must comply with the FDA Requirements.

For several scenarios, the FDA requires that some kind of problems or defects found in the product, even before it is released to the market, to be analyzed and documented. For these matters, the reason to do an RCA is to be aligned to the requirements of the FDA.

Group Expertise

There are defects that even though are not safety issues nor required to have follow-up by FDA requirements, present a big threat under the judgment of a group of experts. Therefore, having the motivation to avoid such problem to grow and become one of the previously mentioned kinds of defects, it will trigger the creation of an RCA for find its source and solve it at the earliest phase possible.

Trending

It is possible that most of the defects managed have a common characteristic. It is possible as well that given that such problems are not in the previously mentioned triggers, never get to be analyzed to find the root cause. It is a waste of effort solve every time the same problem if there is no effort to try to solve the source. This is the main reason because Trending is taken into account as an RCA Trigger.

The goal is to create an RCA of the defect that has most iteration or repetitions on the development process, the purpose would be to improve the process and therefore eliminate the defect from its source.

Customer Feedback

This category can be seen as the extension of the voice of the customer thus it can be heard. The defects or problems found in the field by the customer can be analyzed with the same tool as the defects found on the development process.

The reason for not setting this trigger more above on the rank is because the main purpose is to solve the problems before the product reaches the customer. Nevertheless, this information can also be of profit for current and future projects.

Product Improvement Project

The last trigger has the purpose of improve the quality of the product. It is divided in two categories; reliability and performance.

Reliability

The idea is to analyze the defects or lack of reliability of some aspect of the equipment at system integration phase. The ultimate purpose is to understand the reasons that decline the reliability and solve it.

This would help to increase reliability of parallel and future products as well.

Performance

The idea is to analyze the defects that decline the performance of some aspect of the equipment at system integration phase. The ultimate purpose is to understand why the poor performance was created and solve it to enhance the performance of that specific product as well as parallel and future ones.

Defect Introduction Influencing factors

1. Developer Capability:

   The professional Knowledge and experience possessed by individual developers that is required to perform their development tasks. This includes subjects like development processes, environments, tools, and languages.

2. Domain Knowledge:

   The professional knowledge possessed by the individual developers about the product, its architecture, its intended usage, its users, and application or operating environment.

3. Team Composition:

   The collection of individuals in a development team based on a balance of individual expertise, skill levels, and personal qualities. The development team has a certain size and may have a complex structure in terms of hierarchy and reporting lines and may have its own position in a larger project organization.

4. Team Distribution:

   The distribution of development activities over geographically-separated locations, possible involving development activities at locations with other cultures and in different time zones.

5. Collaboration:

The interaction between individuals with the purpose to achieve a common goal. The sense of being a team strengthens cooperation, personal relationships, trust, stability, and continuity of the team. Collaboration also is relevant to parties outside their own development team like clients, end-users or subcontractors.

6. Business Management Maturity:

   The stability, management style, and support of the business' senior management in decision making related to product development. Maturity is also determined by the experience of business management with the product to be developed and with managing the type of project that produces it.

7. Product Complexity:

   The technical complexity of the product to be developed in terms like size, interfaces, innovative features, technical constraints, reuse, algorithms or processing.

8. Communication:

   The exchange of information between stakeholders about changes in the project or the product. Adequacy of communication is determined by speed, communications media, honesty, openness, and communicative skills of the people involved.

9. Project Management Maturity:

   The maturity of performing all activities required for properly managing the project. This includes proper project planning, monitoring, and control – specifically the assignment of responsibilities and alignment of activities and processes with relevant stakeholders in development and testing.

10. External Disturbance:

    All unforeseen events that interrupt the project activities and that cause development to deviate from the initial plan.

11. Process Maturity:

    The extent to which processes are explicitly defined, managed, measured, controlled, and effective. This includes development processes, requirements engineering and management, quality assurance, configuration management, knowledge management, subcontract management.

12. Change Control:

    The monitoring and control of changes in the product and its requirements and specifications.

13. Quality of Documentation:

The quality and completeness of project and product documentation that is generated throughout the development lifecycle and to support the development activities.

14. Requirements:

    The quality and completeness of the requirements required as input to the development activities, Quality and completeness prevent ambiguity, misinterpretation, misassumption, and implicitly with regard to requirements. Continuous changes, or a continuously increasing number of requirements, influence the requirements stability.

15. Development Environment:

    The availability and stability of software, hardware, tools, platforms and other resources that compose the infrastructure for developing the product.

16. Innovation:

    The usage and maturity of new technologies applied in the development of the product.

Cause-and-Effect Diagram (CED)

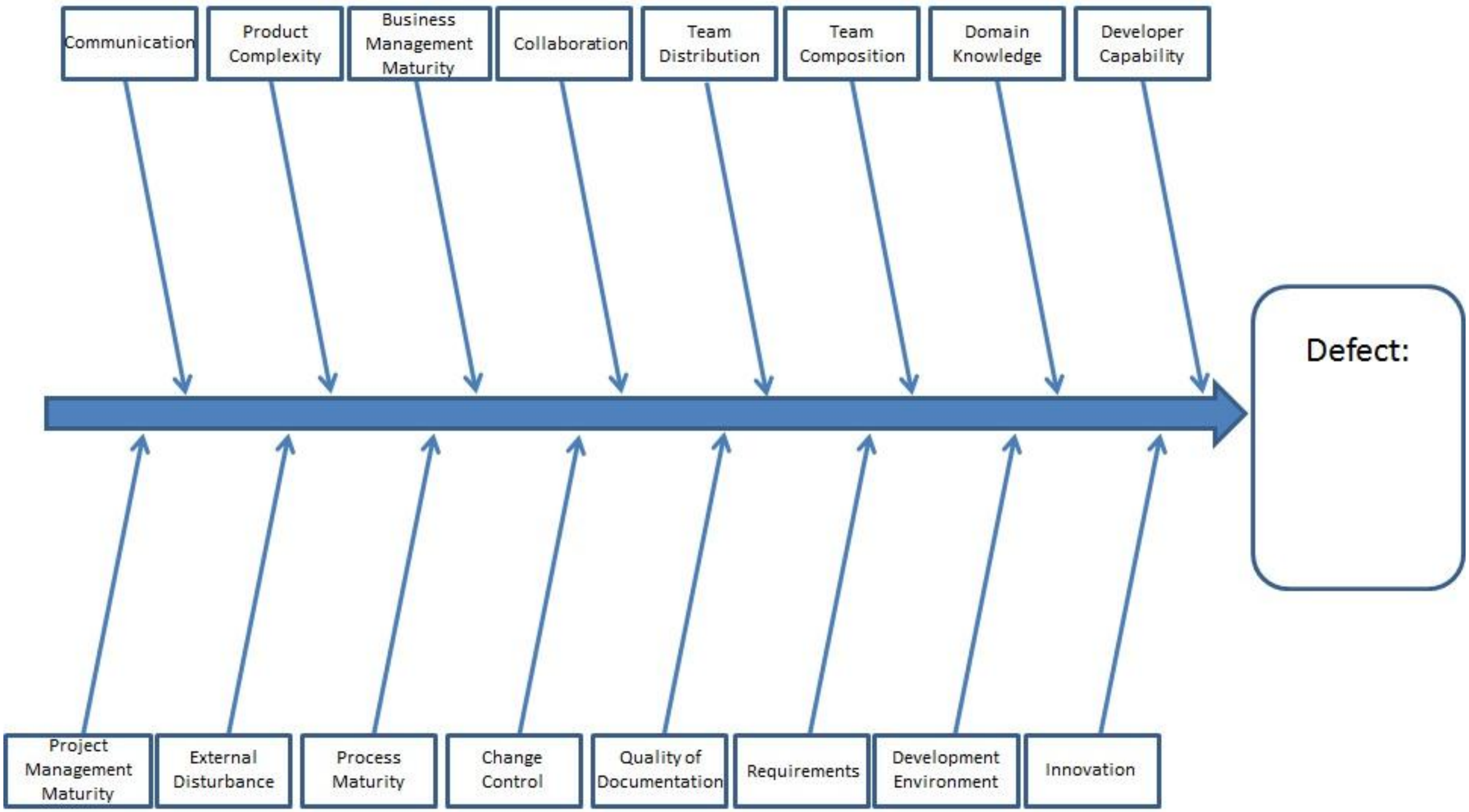


Figure 16. Cause-and-Effect Diagram (CED) with Defect Introduction Categories

Problems Detected

This is the list of the problems to be analyzed.

N	Submitted On	ID	Headline	Submitter	Project	Severity	Safety
1	**2012-02-09 14:25**	MR00113347	sar model for head and knee rx coils for pediatric application	Cecilia Possanzini	obelix	1-Critical	Yes
2	**2011-10-07 13:36**	MR00109527	Enhanced MR Spectroscopy Output has X and Y exchanged in implicit Voxel Order	Henri Matthijsse n	obelix	1-Critical	Yes
3	**2011-11-01 12:17**	MR00110131	Phase drift correction does not work for daisy chained rxe's	Bart Voermans	obelix	1-Critical	No
4	**2011-10-18 15:59**	MR00109791	Shimtrays of gradient coil WA Sometimes not interchangeable and dust in the tubes	John Huijbregts	obelix	1-Critical	No
5	**2011-09-08 10:42**	MR00108838	WB SAR LUT Breast Ingenia needs to be changed	Cecilia Possanzini	obelix	1-Critical	No

N	Submitted On	ID	Headline	Submitter	Project	Severity	Safety
6	**2011-07-28 16:41**	MR00107899	Impossible to landmark Breast Coil without whole body option	Patrick Schmetz	obelix	2-Major	No
7	**2012-03-28 13:29**	MR00114815	SED crashed after switching system in another language	Peter Memel	obelix	3-Average	No
8	**2011-11-21 15:47**	MR00111157	3.0T AC IQ spec is not the latest version	Patrick Schmetz	obelix	3-Average	No
9	**2011-11-17 21:35**	MR00111033	Possible failure of the stop button at the magnet on several sites.	Linus Wittens	obelix	3-Average	No
10	**2011-09-01 11:15**	MR00108694	SWO: Bore light holder melted.	ClearQuest TrackWise Interface	obelix	3-Average	No

Appendix 5: Outcome of RCA Validation Session

RCA Pilot Session

Attendance:

- Ad Machielsen
- Patrick Schmetz
- Jan van Moll
- Daniel Vallejo

Methodology:

1. Explanation of the Handed-In document
    a. RCA invitation: Characteristics and purpose of the session
    b. RCA Triggers: Explanation of the method to decide whether a defect requires or not a Root Cause Analysis
    c. Defect Introduction influencing factors: Explanation of what this influencing factors roll is within the RCA Tool selected and its meaning
    d. Cause-and-Effect Diagram (CED): Explanation of the fine-tuned CED with the DI influencing factors as categories and how should it be read and used
    e. Show the list of defects and explain the order chosen to be discussed
2. Brief introduction to the RCA Pilot Session
    a. Explanation of the Goal of the session : Making clear the evaluation is not to be done over the resulting root cause, but more about the feasibility and feedback of the session itself
    b. Explanation of the Process Developed: Focusing on the three aspects related to the RCA Session (Decision of Accepting the PR, Decision of Risk Analysis, RCA Session)
    c. Show expected steps to be developed during the discussion of every defect
    d. Show example of a Filled CED
3. Beginning of Brainstorming
    a. Targeting to develop the CED and RCA of 5 out of 10 defects listed
4. Evaluation of the Session
    a. Opinion and Suggestions

Analysis of the Listed Defects

D1-SAR model for head and Knee RX coils for pediatric application

Causes Listed:

- No preparation of Use Cases
- Recurrence on the defect
- Several owners of process

Root Cause Concluded:

- Frequent transfer of Knowledge and ownership among people on the team has provoked to prevent defect of being solved.

D2- Enhanced MR Spectroscopy Output has X and Y exchanged in implicit Voxel Order

Causes Listed:

- Misinterpretation of DICOM Standards
- Coding error
- Defect not tested before in a low level detection phase
- Previous testing was presumably done in a higher level with not so specific design

Root Cause Concluded:

- Apparently a coding error caused this effect, but more evidence is needed to discard the misunderstanding the DICOM standard

D3- Phase drift correction does not work for daisy chained RXE's

Causes Listed:

- Provoked as side effect of a different Change
- Lack of documentation of how a change would affect the system
- Change introduced late and without documentation
- Lack in communication from defect known affront
- Problem has been reported but no reaction to solve it
- Lack on update of requirements whenever a change is done
- Not specifying the interaction that changes can have with current design

Root Cause Concluded:

- It was agreed that lack on the update of the requirements and the fact that changes are done without focusing on the system as a whole, but just improving locals caused this effect

D4- Shim trays of gradient coil WA Sometimes not interchangeable and dust in the tubes

Causes Listed:

- Complete new shim trays
- New Technology
- New component
- Manufacturing specs by TESLA (supplier)
- Communication issue among suppliers and Philips

Root Cause Concluded:

- Consensus was found in the aspect that this is a very complex product and a brand new technology, being this the main cause for the problem

D5- WB SAR LUT Breast Ingenia needs to be changed

Causes Listed:

- Incorrect model of verification
- High complexity of the product
- Different locations of the development team with not optimal communication
- Transfers done to Ingenia
- Big change of design in short notice
- Lack of tool of verification

Root Cause Concluded:

- It has been agreed that the fact of having big change on short noticed and not having a tool for verify the component caused the problem

D6- Impossible to landmark Breast Coil without whole body option

Causes Listed:

- Complex machine with different optional capabilities
- Not normal use of equipment
- Pressure to get things done on time
- Change to a coil (component)
- Not analyzing the effects of the change of the component over different components or requirements

Root Cause Concluded:

- The testing of this event is done with all optional capabilities ON, while the defects where found on equipment's with some of those characteristics off, therefore there was a lack of a more specific test phase.

D7- SED crashed after switching system in another language

Causes Listed:

- Low volume recurrent Issue
- No coding to specific language
- Management pressure to get things on time
- No check of completeness

Root Cause Concluded:

- The tests did prepare the slot to set the system in different languages but forgot to add the actual coding in one of those languages charged, so it crashed whenever asked to run in that language.

Evaluation

The session ran smoothly, the people involved in it has already a good amount of experience in RCA. The method of the CED was already understood by them, and once explained the different categories (DI influencing factors) of the CED, it was discussed lightly the meaning of some of the categories which meaning appears to be quite similar.

The team was composed by a multifunctional set of testers, that are experts on their field and that have continuous contact among them. These factors helped to have a smooth session with a productive analysis and debate of reasons or causes for each product defect listed.

If there would be more people, and a more diverse background of knowledge among them, there would be more chance to more disagreement, different reactions and group dynamics behavior, which does not really means a neither better nor worse experience.

At some point, the debate began first with what they assumed was the Root Cause of the problem, and followed up with a discussion of the not so deep causes, giving logic to their decisions.

The CED template was handed in, and the intention was to fill one per defect. Nevertheless, it was not used actively to write Root Causes on it by the participants. On the other hand, it filled the purpose by helping the participants to structure their thinking and setting root causes that were linked to the categories specified on the CED.

Trending and Control

Suggestions

From the participants of the session, different point of views and opinions where recollected, both in the format of straightforward session evaluation and recommendations, as well as comments given during the session itself.

It is clear that the session was taken with good esteem from the part of both participants, nevertheless some interesting suggestions where given.

It was very well accepted the fact of having a pre-defined structure for the given tool to use (the Ishikawa diagram in this case). Pointing out that the fact of having already a categorized structure is something desirable because it helps to focus in special causes of some category that otherwise would not occur to them. It was declared that it can be used in CAPA sessions, given that the categorization can create sessions that would be clearer and less prone to be lost by the participants.

The agreement that this kind of sessions would be helpful and it should be done in a more regular basis; nonetheless, it seems unrealistic to have them for every single problem or defect, being more possible to agree to implement this sessions with "buckets" of defects that qualify for the RCA given the stage of development and severity.

It was also found that the participants regard this event or tool as productive for improving the organization, not only processes or products. One example would be to re do the RCA session once the problem was solved in order to improve the high level of the organization.

The idea of having "buckets" was not only used for the problems, but also it was mentioned that this sessions could have as output a counting of the declared "Root Causes" that could be used afterwards to create buckets of causes, getting to know more about the organization and what is provoking a great amount of sever problems among the organization.

Appendix 6: Logic grounding the Degree of fitness between RCA Tools and Tool Categories

	RCA Tool	Data Driven	Oversight	Multiple Situations
1	CED	None: Is mostly based on the opinion of the people analyzing the problem, and the interaction between them might influence the outcome of the tool.	High: It offers the view of several focalized categories towards a single problem offering different perspectives for finding potential causes.	None: It is focalized on analyzing only one problem at a time. Its purpose is to select one Root Cause from the analysis done.
2	Matrix Diagram	High: If there is data available is much easier to construct the matrix, moreover the system to relate the causes to the effects is based on grades.	Low: It offers some oversight of the problem, nonetheless the detail of the oversight depends on the ability of selection of causes and effects before grading their interaction.	None: The purpose of the matrix is to select the highest potential cause and select it as the root cause.
3	Five Whys	None: Is mostly based on the opinion of the people analyzing the problem, and the interaction between them might influence the outcome of the tool.	High: It offers the view of several branches of the problem and helps to construct cause and effect relationships.	High: It allows the analysis of different branches of investigation with different levels of deepness and is possible to find more than one root cause
4	ID	High: If there is data available is much easier to construct the interrelationship diagram as the data can show trends and correlations. Moreover the system to find key effects and main causes is numerical based on the income and output of each Factor.	Low: It offers some oversight of the problem, nonetheless the detail of the oversight depends on the ability of selection of causes and effects before grading their interaction.	None: It can only analyze the interrelationships of different factors with one specific problem in mind, even though it can find several main causes, all of them are related to the same situation.
5	Fault Tree Analysis	High: If there is data available is much easier to construct the three as the data can show trends and correlations.	High: It offers the view of several branches of the problem and helps to construct cause and effect relationships.	High: It allows the analysis of different branches of investigation with different levels of deepness and is possible to find more than one root cause. It explicitly allows the 'OR' construction
6	CRT	High: If there is data available is much easier to construct the three as the data can show trends and correlations. Moreover, the specific constructs and the Categories of Limited Reservation make this tool very data driven as proofs need to be approved.	High: It offers the view of several branches of the problem and helps to construct cause and effect relationships. The restriction of sufficiency makes this tool very powerful in the sense of giving a relevant and clear overview of the undesirable event.	High: It allows the analysis of different branches of investigation with different levels of deepness and is possible to find more than one root cause.

Appendix 7: Logic grounding the Category selection according to project types defined

Project Type	Characteristic	Description	Data Driven	Oversight	Multiple Situations
I	Content Technology Size	HW Low Large	Not specific need for this category to be fulfilled.	Not specific need for this category to be fulfilled.	This type of projects needs to use tools that are capable of managing multiple situations. Given that the size of the project is large, most likely there will be high amount of interactions and factors to analyze.
II	Content Technology Size	HW Low Small	Not specific need for this category to be fulfilled.	This type of project can profit from tools that exacerbate the oversight because it is a small in size, has low technological innovation and contains only HW. In a sense it can be catalogued a one of the easiest project types for which most likely will not need to explode any other category.	Not specific need for this category to be fulfilled.
III	Content Technology Size	HW+SW High Large	The specific Project characteristic that triggers the need of data driven tool is having either High technological innovation and includes Software content.	Not specific need for this category to be fulfilled.	This type of projects needs to use tools that are capable of managing multiple situations. Given that the size of the project is large, most likely there will be high amount of interactions and factors to analyze.
IV	Content Technology Size	HW High Small	The specific Project characteristic that triggers the need of data driven tool is having High technological innovation.	Not specific need for this category to be fulfilled.	Not specific need for this category to be fulfilled.
VI	Content Technology Size	SW Low Small	The specific Project characteristic that triggers the need of data driven tool is having Software content.	This type of project can profit from tools that exacerbate the oversight because it is a small in size, has low technological innovation.	Not specific need for this category to be fulfilled.
VII	Content Technology Size	SW High Large	The specific Project characteristic that triggers the need of a data driven tool is having either High technological innovation and includes Software content.	Not specific need for this category to be fulfilled.	This type of projects needs to use tools that are capable of managing multiple situations. Given that the size of the project is large, most likely there will be high amount of interactions and factors to analyze.

Appendix 8: Practical Handbook Delivered to Philips Healthcare

Root Cause Analysis Tool Selection Approach

August 15
2012

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R&D Excellence
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Thesis Project

This document presents an approach to select one of the Root Cause Analysis tools, given the valorization of different categories previously defined to make a problem evaluation. The purpose of the approach is to guide through the Selection and utilization of the RCA tool.

Contents

Introduction

This document includes different tools used in the practice to elaborate Root Cause Analysis. The objective of this kind of analysis is to find the factors to be solved no only to correct the product defect found, but to avoid that it happens again.

For this purpose, and regardless the tool or method chosen to develop the analysis, the literature offers recommendations to succeed in the discovery of the Root Causes, recommendations as the following:

1. Clearly define the problem and its significance to the problem owners.
2. Clearly delineate the known causal relationships that combined to cause the problem.
3. Clearly establish causal relationships between the root cause(s) and the defined problem.
4. Clearly present the evidence used to support the existence of identified causes.
5. Clearly explain how the solutions will prevent recurrence of the defined problem.
6. Clearly document criteria 1 through 5 so others can easily understand the logic of the analysis.

(Gano D. L., 2011)

It is important to remember that the RCA should address the problem and state the root cause found through the analysis done. It is not the purpose of the RCA to promote specific solutions for the given problem. There should be a clear division between explaining how solutions will prevent future recurrence of an effect, and explaining the solution to implement which goal is avoid recurrence.

Comparison of Tools

The tools here presented have different characteristics. For this reason, below is presented a figure with the purpose to help and guide the selection of the RCA Tool more appropriate for the problem faced.

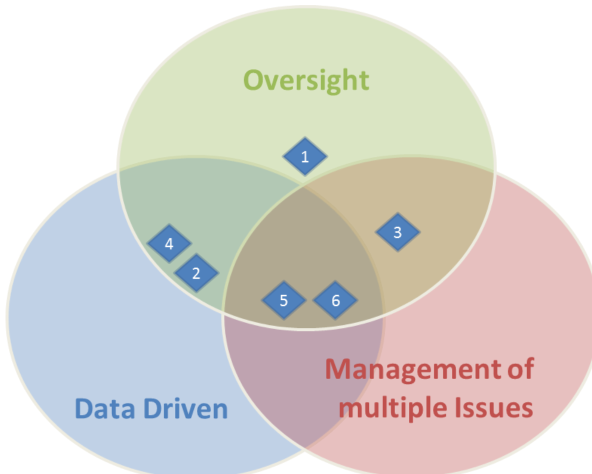


Figure I Distribution of the RCA Tools among Categories

Because differences in the projects managed among the same organization cannot be treated with the same tools if there is focus on efficiency on the problem solving. There are characteristics of the projects that incite different reactions from the management.

Table I Different Type of Projects among the Software-Intensive organization

Project Type	Characteristic	Description	Example
I	Content	HW	ROHS
	Technology	Low	
	Size	Large	
II	Content	HW	Body Coil Deluxe Board
	Technology	Low	
	Size	Small	
III	Content	HW+SW	Obelix
	Technology	High	
	Size	Large	
IV	Content	HW	New RXES
	Technology	High	
	Size	Small	
V	Content	SW	?
	Technology	Low	

	Size	Large	
VI	Content	SW	A Functionality
	Technology	Low	
	Size	Small	
VII	Content	SW	Himalaya, complete new SW UI
	Technology	High	
	Size	Large	
VIII	Content	SW	? = First steps in technology involvement
	Technology	High	
	Size	Small	

The purpose of this section is to elaborate on the previously mentioned characteristics of both, the projects and the tools. Once the characteristics are explained and is stressed the need to take them into account, a comparison matrix for the categories of the tools will be shown to illustrate de degree of compliance of each tool.

Table II Comparison of Characteristics included on each RCA Tool

	RCA Tool	Oversight	Data Driven	Multiple Situations
1	CED	2	0	0
2	Matrix Diagram	1	2	0
3	Five Whys	2	0	2
4	ID	1	2	0
5	Fault Tree Analysis	2	2	2
6	CRT	2	2	2

Once visualized the categorized tools, a new matrix will illustrate what category, fits best to initiate a root cause analysis for a given type of project.

Table III Guide for RCA Tool Selection according to Project type

Project Type	Data	Oversight	Multiple Situations
I			x
II		x	
III	x		x
IV	x		
VI	x	x	
VII	x		x

Having this guidance, the participants of the teams are free to choose among the tools that best fit on the specific problem for the given project type. In the next section of this document it is offered a guideline of what is the logic of each tool, how are them used, a solved example of each one and a blank template to motivate the beginning of the session with a given RCA Tool.

Cause-and- Effect Diagram (CED)

The Cause-and-Effect Diagram (CED) is classified as a Root Cause Identification tool by (Andersen & Fagerhaug, 2006).

Invented by Kaoru Ishikawa is also known as the Ishikawa diagram or the Fishbone diagram. Its main purpose is to understand what causes a problem.

How to Use It?

The CED is intended to be a tool to expose the ideas of a multifunctional team. Therefore is important that all the team can see what is being edited or developed from a unique source. (e.g. projection of a diagram being edited on a computer or a Diagram being filled in a board in front of everyone.)

It is also important to provide all the participants with a blank template where they can write down their own thoughts before they can share them out loud to all the participants and to promote debate since it is also important to analyze which category is responsible for a given phenomenon.

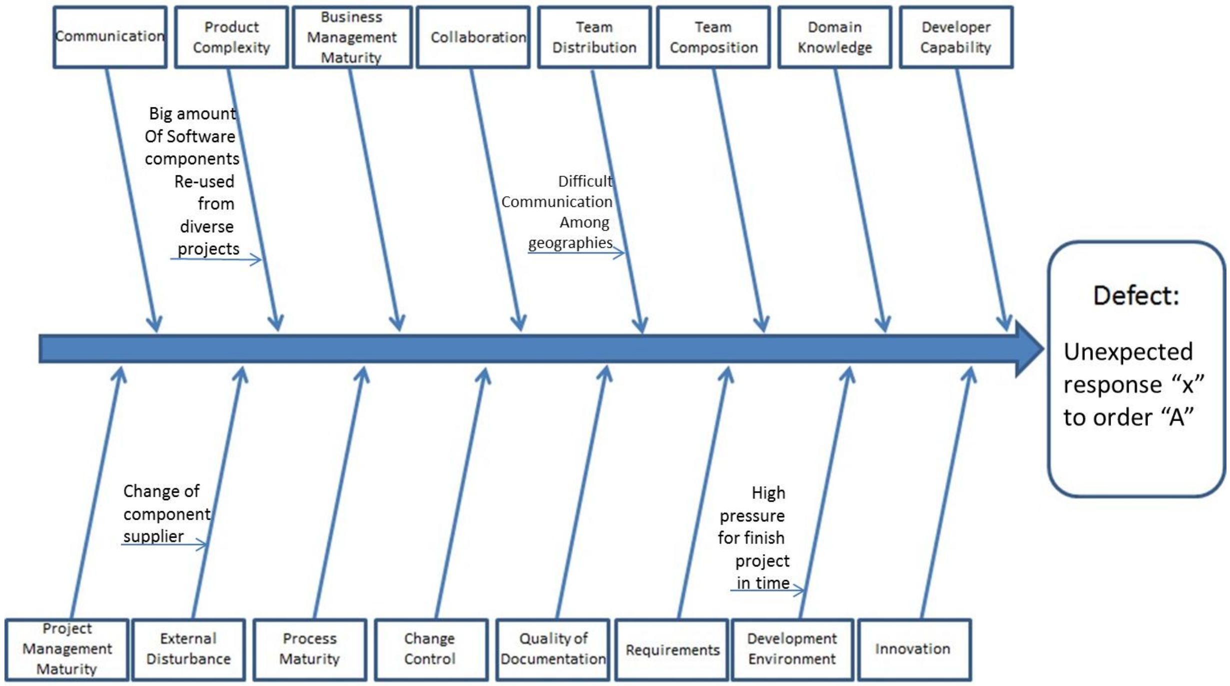
The following are the steps recommended when attempting to do a complete and conscious CED.

1. Clearly describe the problem for which causes are sought
2. Draw the problem at the right end of a large arrow (e.g. Template's area "Defect")
3. Brainstorm and write all possible causes in the applicable area(s) of the chart one main category at a time. Write causes that belong under more than one category in all relevant positions.
4. Analyze the identified causes to determine the most likely root causes.

At the end is expected that the groups agrees on a main cause for the defect discussed. This is achieved by the means of debate and idea sharing; trying to explain the reasons why each cause is responsible for an effect.

Once the groups have agreed on a specific cause (or combination of causes), then should be written down the logic that give ground to these Cause-and-Effect phenomenon. It should be written down the main reasons in order to track the path followed to conclude that the defined root cause indeed creates the effect known as defect in this case.

Example



Root Cause:

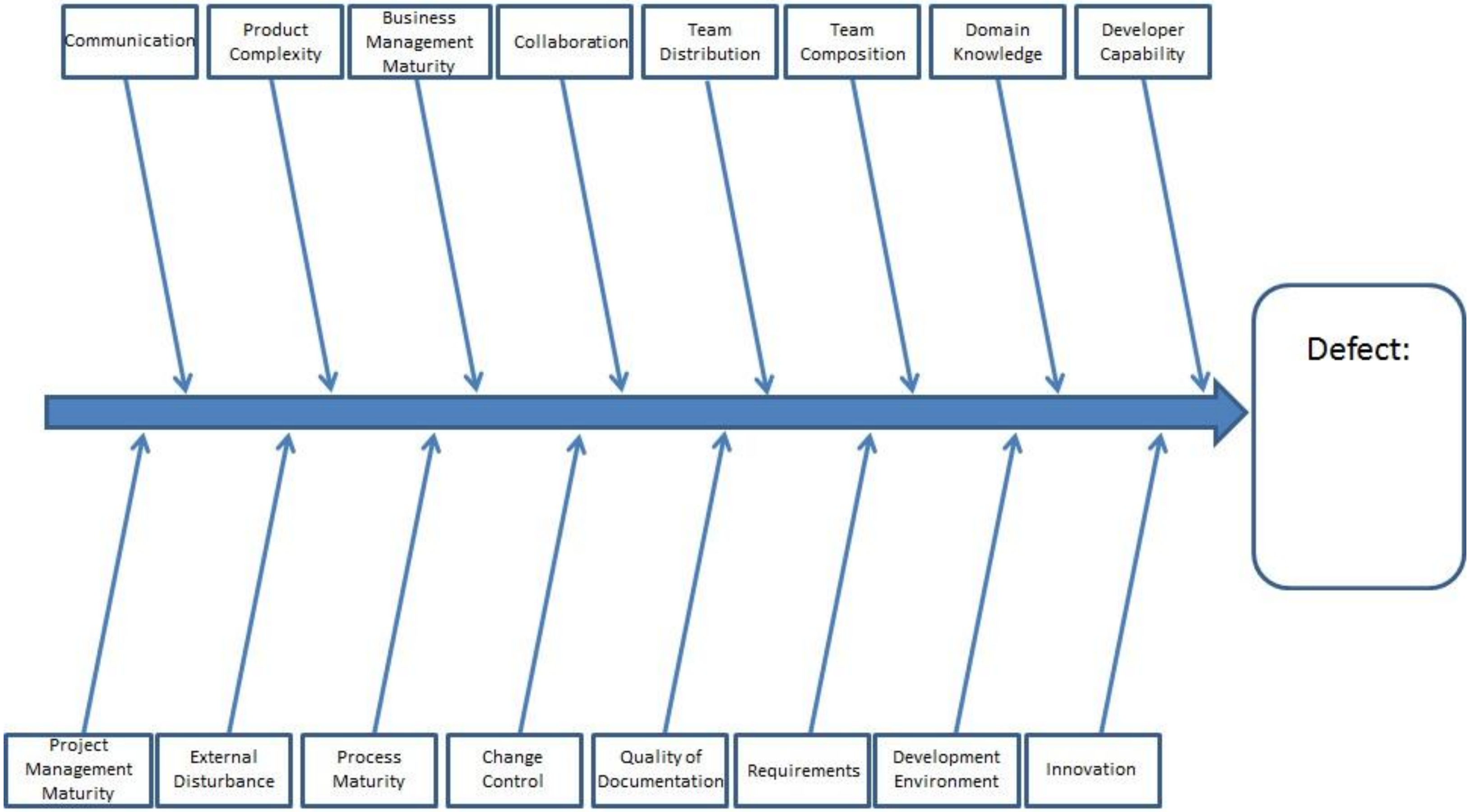
The **interaction of the** software is not optimal due to the big amount of **re-used software components form diverse projects**, being this software developed in three different locations.
The nature of the different projects was not exactly the same, and even though the purpose of the given sections of software was supposed to be compatible, the fine details still need to be tuned.

Responsible(s) for solving problem:

1. Name: Checkpoint Date:
2. Name: Checkpoint Date:
3. Name: Checkpoint Date:

Template

Categories taken from (Jacobs & van Moll, 2007)



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Matrix Diagram

It allows the investigation of a number of possible causes simultaneously and determines which contributes most to the problem being analyzed. It can be used for

- Mapping the overall impact of different possible causes of the problem
- Determining which of many causes is the most prominent

(Andersen & Fagerhaug, 2006)

How to Use It?

In RCA the most used matrix is the L-shaped where one axis shows the characteristic of the problem or defect and the other axis shows the potential causes. The idea is to evaluate in the cell representing the intersection between the problem and the cause, how high their relationship is.

1. Select the problem characteristics and possible causes to be analyzed for types and levels of relationships
2. Plot the variables on the diagram
3. Indicate impacts
4. For each column calculate the total impact and present the sum

Most likely, the cause evaluated with the highest value is the one claimed to be the root cause, or at least the deeper cause of those evaluated.

For simpler evaluation decisions, (Andersen & Fagerhaug, 2006) suggest using a set of symbols with predefined values. This is presented below.

Relation	Symbol	Weight
Weak	△	1
Medium	○	3
Strong	⊙	9

Figure II Symbols and Weights

Once the groups have agreed on a specific cause (or combination of causes), then should be written down the logic that give ground to these evaluation. It should mention the main reasons in order to track the path followed to conclude that the defined root cause indeed is the one that influences the most the effect founded.

Example

Defect: Excessive delay on system reaction when action "X" is requested		Possible Causes		
		Poor HW Connectivity	Insufficient processing power	Complicated Program Script
Problem Characteristics	System Performance Drops	△	⊙	△
	Force quit commands do not work		○	⊙
	Interface Freezes until systems finishes		△	
	Intermittent effect	△		△
	Total Score	2	13	11

Root Cause:

The **Insufficient processing power is** found the **major cause of the excessive delay on system reaction when the action "X" is requested**, due to the strong **relationship to the drop of the system** performance, also proved by the sign that it has a medium relationship **with the failure of the force quit commands and** weak relationship to the fact that the **Interface freezes** until the system finishes.

Responsible(s) for solving problem:

1. Name: Checkpoint Date:
2. Name: Checkpoint Date:
3. Name: Checkpoint Date:

Template

Relation	Symbol	Weight
Weak	△	1
Medium	○	3
Strong	⊙	9

Defect:		Possible Causes									
		Cause A	Cause B	Cause C	Cause D	Cause E	Cause F	Cause G	Cause H	Cause I	Cause J...
Problem Characteristics	Characteristic 1										
	Characteristic 2										
	Characteristic 3										
	Characteristic 4										
	Characteristic 5										
	Characteristic 6										
	Characteristic 7										
	Characteristic 8										
	Characteristic 9										
	Characteristic 10										
	Total Score										

NOTES:

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Five-Whys

The inherent nature of the Five-Whys is to investigate even more deeply into the levels of causes. Its main purpose is to constantly ask "Why?" when a cause has been identified, thus progressing through the levels toward the root cause. It can be used to:

- Question either each identified cause is a symptom, a lower-level cause, or a root cause
- Continue the search for true root causes even after a possible cause has been found

(Andersen & Fagerhaug, 2006)

This method is quite useful when used on minor problems that require nothing more than some basic discussion of the event. It identifies causal relationships but still subscribes to the root cause myth of first finding the root cause and then assigning solutions. It is perfectly acceptable for informal discussions of cause (Gano D. L., 2007).

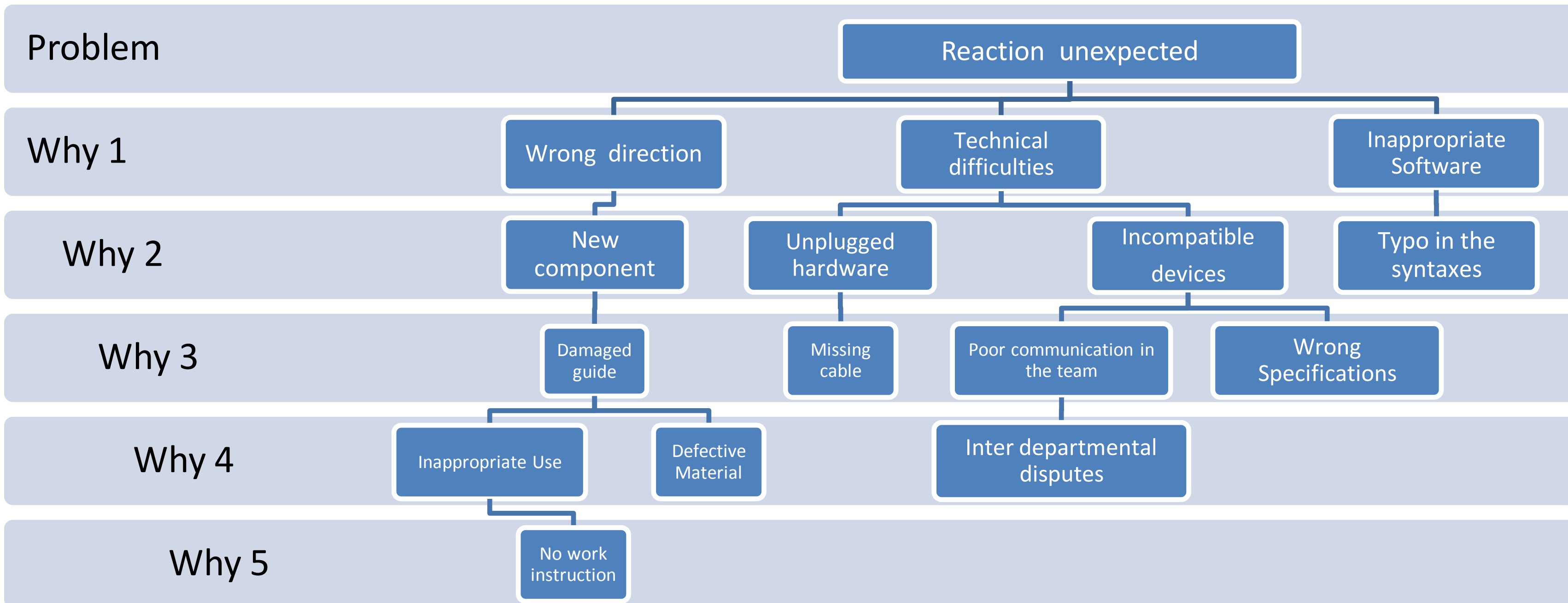
How to Use It?

Since the Five Why method is a straightforward questioner over the problem found, it is important to state in a clear manner the defect found.

1. Once the problem has been identified, ask "Why (Problem Identified)?"
2. Keep the most objective answer and note it as A1. (Note that it is possible that the problem has more than one answer. Then bear in mind you will keep the procedure with each one of those answers [e.g. A1.1, A1.2, A1.n])
3. Ask again "Why (A1)" and take note of the answer as "A2"
4. Repeat steps 2 and 3 with the new answers until there is no more useful information.

The Five is just an arbitrage, and does not mean that every root cause is exactly at the fifth "why". The root cause has been identified when asking "why" does not provide more useful information. This method produces a linear set of causal relationships and uses the experience of the problem owner to determine the root cause and corresponding solutions. A popular graphical representation of the "Five-Whys" is the "Why Staircase" (Gano D. L., 2007).

Example



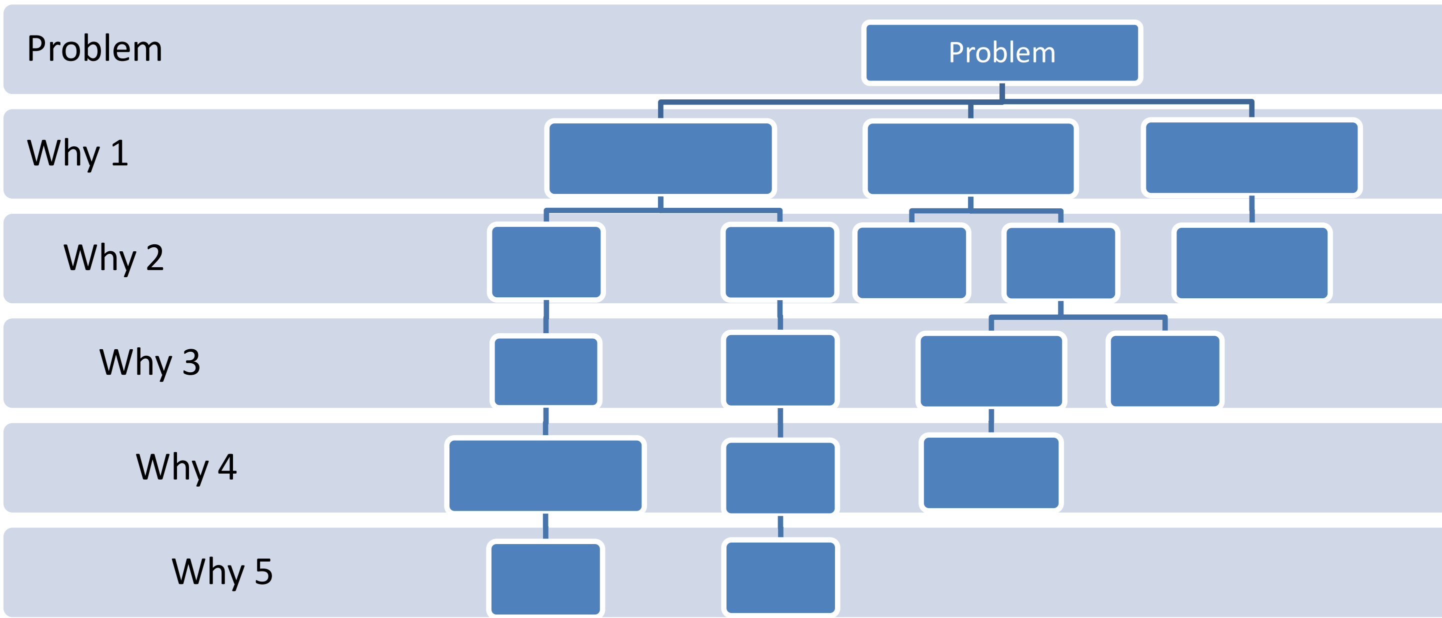
Root Cause:

The **Insufficient processing power is** found the **major cause of the excessive delay on system reaction when the action "X" is requested**, due to the strong **relationship to the drop of the system** performance, also proved by the sign that it has a medium relationship **with the failure of the force quit commands and** weak relationship to the fact that the **Interface freezes** until the system finishes.

Responsible(s) for solving problem:

1. Name: Checkpoint Date:
2. Name: Checkpoint Date:
3. Name: Checkpoint Date:

Template



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Fault Tree Analysis

Fault Tree Analysis (FTA) is used in the design stages of a project and works well to identify possible causal relationships. It requires the use of specific data regarding known failure rates of components. Causal relationship can be identified with "and" and "or" relationships or various combinations thereof.

It is normally not used as a root cause analysis method, primarily because it does not work well when human actions are inserted as a cause. This is because the wide variance of possible human failure rates prevents accurate results. But it works extremely well at defining engineered systems and can be used to supplement an RCA in the following ways.

1. Finding causes by reviewing the assumptions and design decisions made during the system's original design
2. Determining of certain causal scenarios are probable
3. Selecting the appropriate solution(s)

(Gano D. L., 2007).

The main difference between the FTA and the majority of the tools also presented is the fact that it recognizes that in many situations, possible causes are related or belong to groups of similar issues.

Therefore it is useful for portraying all possible causes in one diagram and identifying such links and naturally builds on the results from five whys analysis. Its purpose is to:

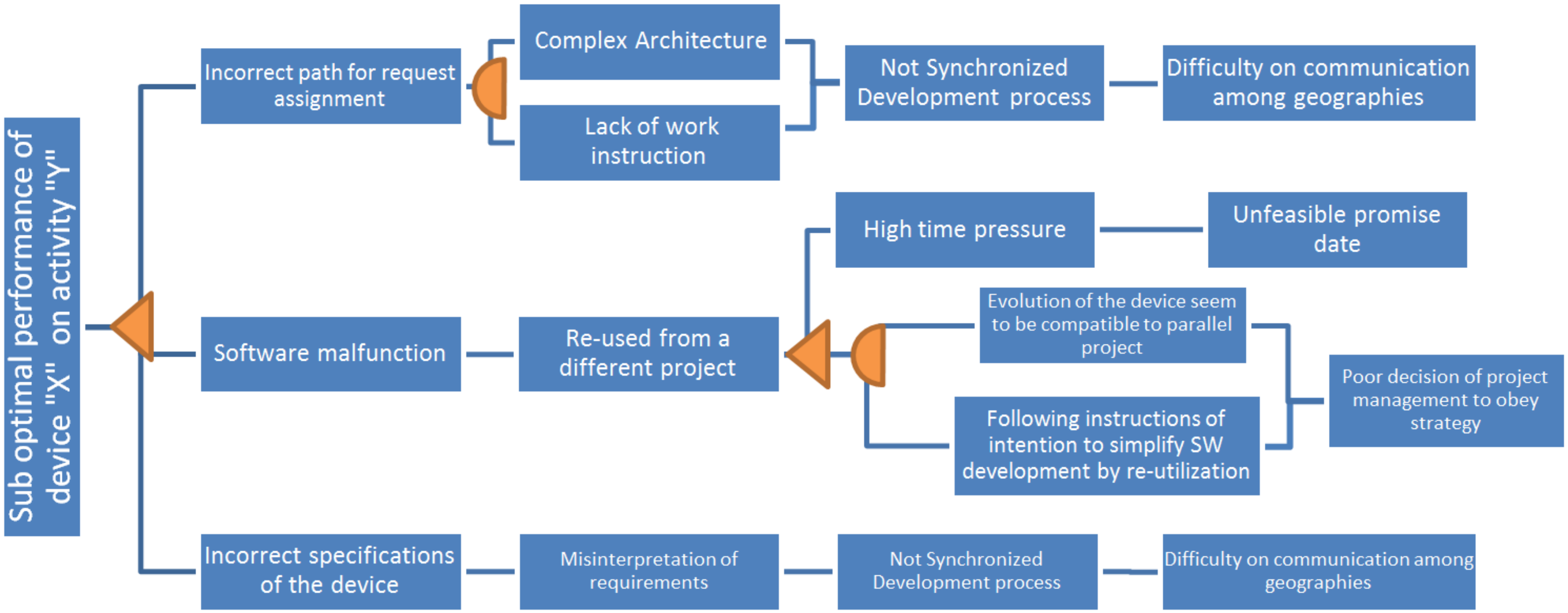
- Produce a clear overview of the possible causes identified
- See linkages between causes or identify groups of related causes

How to Use It?

1. Identify the problem to be analyzed and place it at the top of the tree diagram (this is the top event)
2. Brainstorming immediate causes at the level below the top event and plot these on the diagram respectively
3. For each cause identified, assess whether it is the result of lower-level causes or represents a basic cause. Draw circles around basic causes not to be developed further and draw rectangles around intermediate causes.
4. For each that is not a basic cause, repeat steps 2 and 3 until tree diagram contains only basic causes at the lowest level of each branch
5. In the case of more than one cause leading to the level above, use symbols to connect the branches in the diagram to indicate whether these operate together (and, symbolized by ◓) or on their own (or, symbolized by ▲)

(Andersen & Fagerhaug, 2006).

Example



Root Cause:

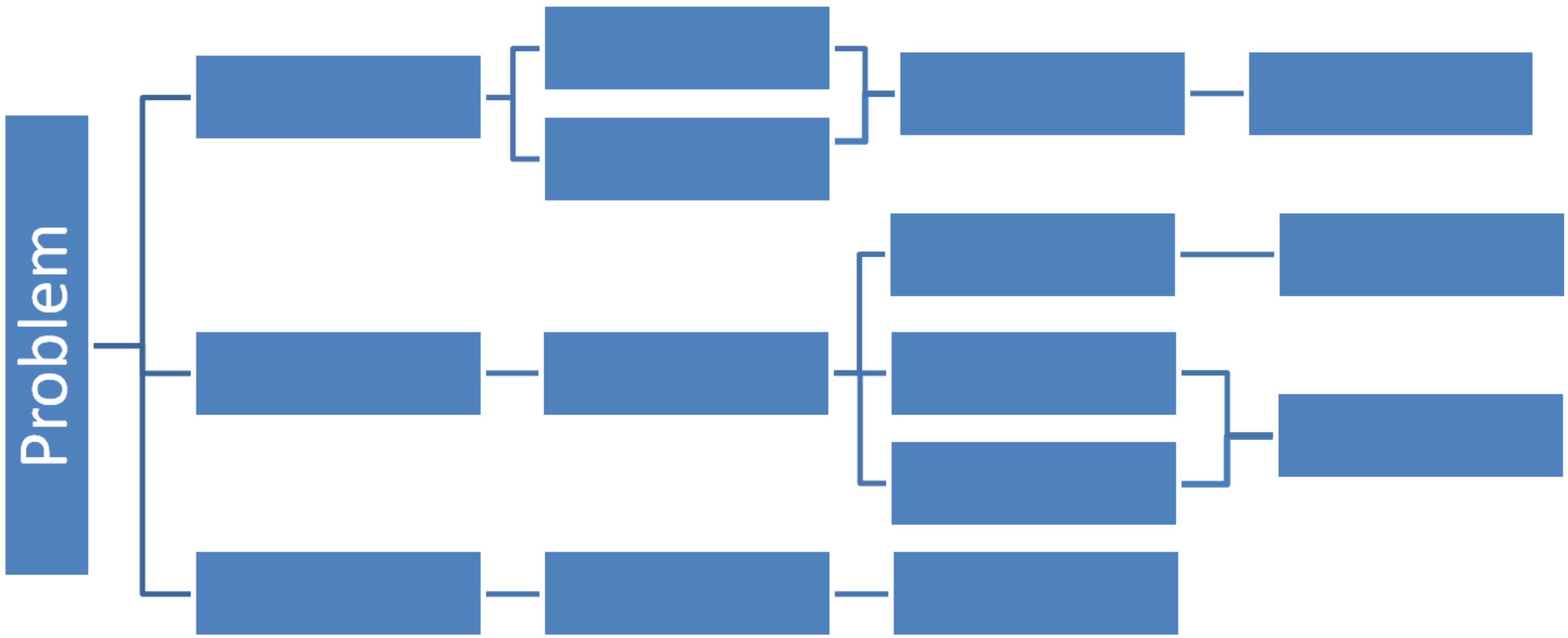
It is found that the **sub optimal performance of device "X" on activity "Y"** is **caused by three main streams, Incorrect path for request assignment**, which **basic cause is the Difficulty on communication among geographies** for the development team; **the second stream is software malfunction** and it was found the **unfeasible promise date** of release **or** the **Poor decision of project management to obey organizations strategy** as **basic causes**; **or** the third stream is **incorrect specifications of the device** which basic cause is again the **difficulty on communication among** geographies for the development team.

Responsible(s) for solving problem:

1. Name: Checkpoint Date:
2. Name: Checkpoint Date:
3. Name: Checkpoint Date:

Template

Function	Symbol
AND	
OR	



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Interrelationship Diagram (ID)

It is originally known as the relationship diagram, was developed by the Society of Quality Control Technique Development in association with the Union of Japanese Scientists and Engineers (JUSE) in 1976. It was designed to clarify the intertwined causal relationships of a complex problem in order to identify an appropriate solution.

The interrelationship diagram "…takes complex, multivariable problems and explores and displays all of the interrelated factors involved. It graphically shows the logical (and often causal) relationships between factors" (Doggett, 2005)

It is mainly used to identify logical relationships in a complex and confusing problem situation. The strength of an ID is its ability to visualize such relationships. Its pain purpose is to help identify relationships that are not easily recognizable, particularly useful for:

- Understanding how different aspects of the problem are connected
- Seeing relationships between the problem and its possible causes that can be further analyzed

(Andersen & Fagerhaug, 2006).

How to Use It?

The steps to use the Interrelationship diagram are the following:

1. Determine the factors to be analyzed for possible relationships and label these using brief and concise definitions.
2. Plot the factors on an empty chart on a whiteboard, preferably in a roughly circular shape.
3. Assess what impacts each factor and which factors are impacted by it, and illustrate the relationships using arrows.
4. After all relationships have been assessed, count the number of arrows pointing into and away from each factor and denote this information on the diagram.
5. Depending on the number of arrows pointing in each direction for a factor, it can play one of two roles: driver (more arrows away from than into), or indicator (more arrows into than away from).
6. When continuing the root cause analysis, the drivers form the starting point.

It is important to slow the process so participants can critically evaluate, revise, examine, or discard factors (Mizuno, ed. 1988). In order to ease the visualization process, (Andersen & Fagerhaug, 2006) recommend determining the label for each factors, and then place them on a whiteboard in a circular shape and assess the relationship of each factor on other factors using arrows.

After all relationships have been assessed, count the number of arrows pointing into or out of each factor. A cause is recognized because it has more arrows going out than those coming in. An effect would be a factor with more "in" arrows than "out".

A variant of the ID is to add the ID matrix, placing all the factors as the values for both axes. This format creates a more orderly display and prevents the tool from becoming chaotic if there are many factors. It is a good technique to force participants to pay attention in a more systematic fashion.

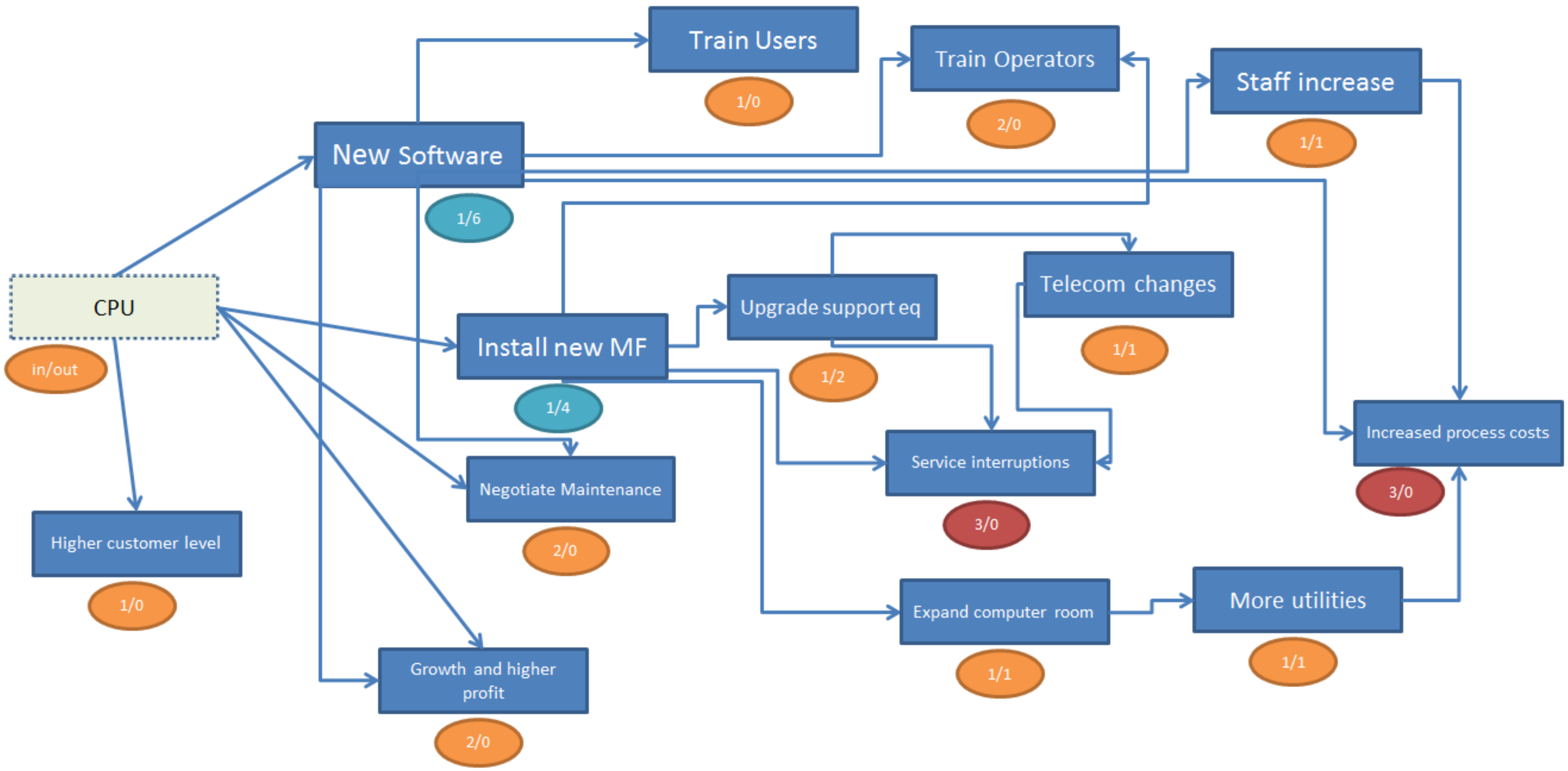
In using this method, it should be able to assess the validity of the choices and the strength of the factor relationships. It is also needed to thoroughly analyze or test the assumptions taken about the problem to make sure it rely on as few subjective judgment about factor relationships as possible (Doggett, 2005).

Example

Example taken from (American Society for Quality, 2004).

Label		Factor
issue	CPU replacement	Issue: Computer Replacement Project
1	New software	Acquisition of new software
2	Install new MF	Installation of new IT mainframe
3	Negotiate maintenance	Negotiation of new contracts for maintenance
4	Growth and higher profit	Expectation of growth and higher profit potential
5	Higher customer level	Expectation of higher customer service level
6	Train users	Need for training of new software to users
7	Train operators	Need for training of new software to operators
8	Upgrade support eq	Need for the upgrade of the support equipment
9	Service interruptions	Service interruptions experienced
10	Expand computer room	Need for Expansion of facilities for major capacity
11	Telecom changes	Changes in the Telecommunications infrastructure
12	Staff increase	Increase on the staff for the organization
13	Increased process costs	Experienced Increased costs
14	More utilities	Need for more utilities as heat, air and electricity

Interrelationship Diagram Matrix	CPU replacement	New software	Install new MF	Negotiate maintenance	Growth and higher profit	Higher customer level	Train users	Train operators	Upgrade support eq	Service interruptions	Expand computer room	Telecom changes	Staff increase	Increased process costs	More utilities	Total Out	
CPU replacement		1	1	1	1	1										5	
New software				1	1		1	1					1	1		6	Basic Cause
Install new MF								1	1	1	1					4	Basic Cause
Negotiate maintenance																0	
Growth and higher profit																0	
Higher customer level																0	
Train users																0	
Train operators																0	
Upgrade support eq										1		1				2	
Service interruptions																0	
Expand computer room															1	1	
Telecom changes										1						1	
Staff increase														1		1	
Increased process costs																0	
More utilities														1		1	
Total In	0	1	1	2	2	1	1	2	1	3	1	1	1	3	1	21	
										Key Effect				Key Effect			



Root Cause:
The interrelationship analysis shows that there are 2 key effects that should be avoided, **service interruption** and the **Increase of process costs.** According to the analysis, the basic causes in which there should be special focus to avoid such effects are the acquisition of **new software** and the need to **install a new mainframe.**

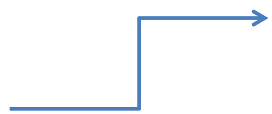
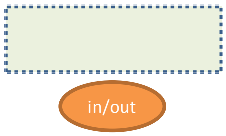
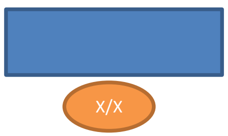
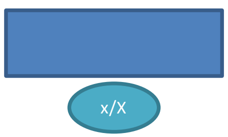
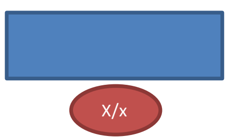
Responsible(s) for solving problem:

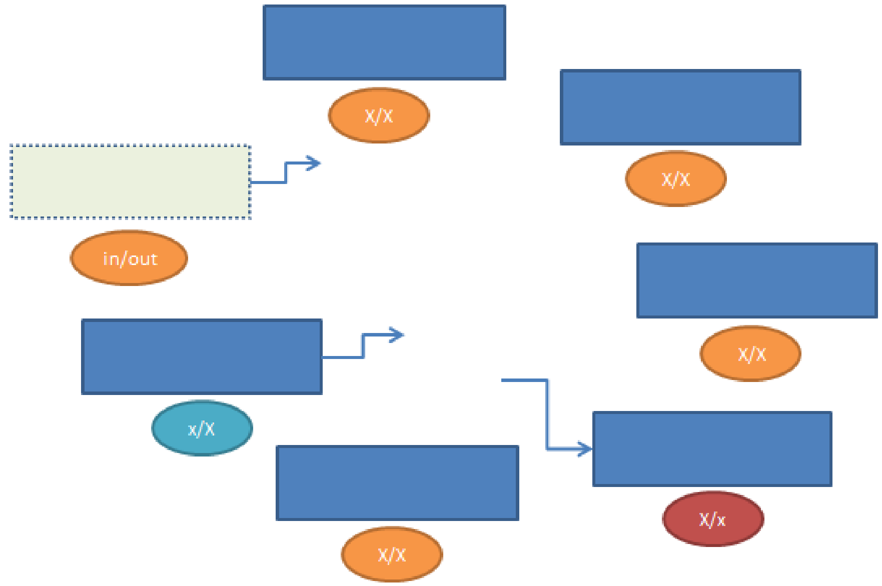
1. Name: Checkpoint Date:
2. Name: Checkpoint Date:
3. Name: Checkpoint Date:

Template

Label		Factor
issue	Problem Label	Issue: Problem
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		

Interrelationship Diagram Matrix	Issue: Problem Label	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8	Factor 9	Factor 10	Factor 11	Factor 12	Factor 13	Factor 14	Total Out
Issue: Problem Label																
Factor 1																
Factor 2																
Factor 3																
Factor 4																
Factor 5																
Factor 6																
Factor 7																
Factor 8																
Factor 9																
Factor 10																
Factor 11																
Factor 12																
Factor 13																
Factor 14																
Total In																

	**Interrelation sign:** The cause factor is the origin of the arrow, the arrow head points towards the effect.
	**Issue Box and Score:** The main problem being analyzed is placed in this box. The score of this issue is not important since it is already identified as the main issue, in this case is used to point the position of the "in/out" score
	**Factor Box and Score:** Before finishing the counting, all factors are in this category. This is the space to place all factors and begin to think on each others relationships. The score respects the order established on the "Issue Box and Score"
	**Base Cause and Score:** The main change with the "Factor Box and Score" is the change on the color of the " Score" space, now colored in green. In this case the 'in' value is considerably lower than the 'out' value
	**Key Effect:** The main change with the "Factor Box and Score" is the change on the color of the " Score" space, now colored in red. In this case the 'in' value is considerably higher than the 'out' value



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Current Reality Three

Is developed by Goldratt and introduced in the book *it's Not Luck* (Goldratt, 1994). The CRT Promotes the idea that the factors of problems are interdependent resulting from a few core causes (root causes), and addresses problems by relating multiple factors rather than isolated events.

Its purpose is to help practitioners find the links between symptomatic factors, called undesirable effects (UDEs), of the core problem. The CRT was designed to show the current state of reality as it exists in a system. It reflects the most probable chain of cause-and-effect factors that contribute to a specific set of circumstances and creates a basis for understanding complex systems (Doggett, 2005).

How to Use It?

The CRT is based on sufficiency, this means that in the CRT each arrow signify a relationship in which the cause is, in fact, enough to create the effect. Entities that do not meet the sufficiency criteria are not connected.

The CRT also uses a unique symbol, the oval, to show relationships between interdependent causes. There may be cases where one cause is not sufficient by itself to create the proposed effect. Thus the ellipse shows that multiple causes are required for the produced effect. These causes are contributive in nature such that it is necessary that all of them to be present for the effect to take place. If one of the interdependent causes is removed, the effect will disappear (Doggett, 2005).

1. Identify the main situation (Problem).
2. List between five and 10 problems or UDEs related to the situation.
3. Test each UDE for clarity and search for a causal relationship between any two UDEs.
4. Determine which UDE is the cause and which is the effect.
5. Test the relationship using categories of legitimate reservation (CLRs). (These are rules for evaluating assumptions and logic and are described later.)
6. Continue the process of connecting the UDEs using "if-then" logic until all the UDEs are connected.
7. Sometimes the cause by itself may not seem to be enough to create the effect. Additional dependent causes can be shown using the "and" connector.
8. Logical relationships can be strengthened using words like some, few, many, frequently, and sometimes.
   (Cox & Spencer, 1998).

The CLRs consist of six test or proofs: Clarity, entity, existence, causality existence, cause insufficiency, additional cause, and predicted effect (Dettmer, 1997). These rules ensure rigor in the CRT process and tare the criteria for verifying, validating, and agreeing upon the connections between factors. They are also used to facilitate discussion, communicate disagreement, reduce animosity, and foster collaboration (Scheinkopf, 1999).

Clarity, causality existence and entity existence are the first level of reservation and are used to clarify meaning and question relationships or the existence of entities. The second level of reservation includes cause insufficiency, additional cause, and predicted effect. They are secondary because they are used when questions remain after addressing first-level reservations. Second –level reservations look for missing or additional causes and additional or invalid effects (Dettmer, 1997) (Scheinkopf, 1999).

Guide to test the factors with the CLR

The Categories previously mentioned are graphically represented as follows.

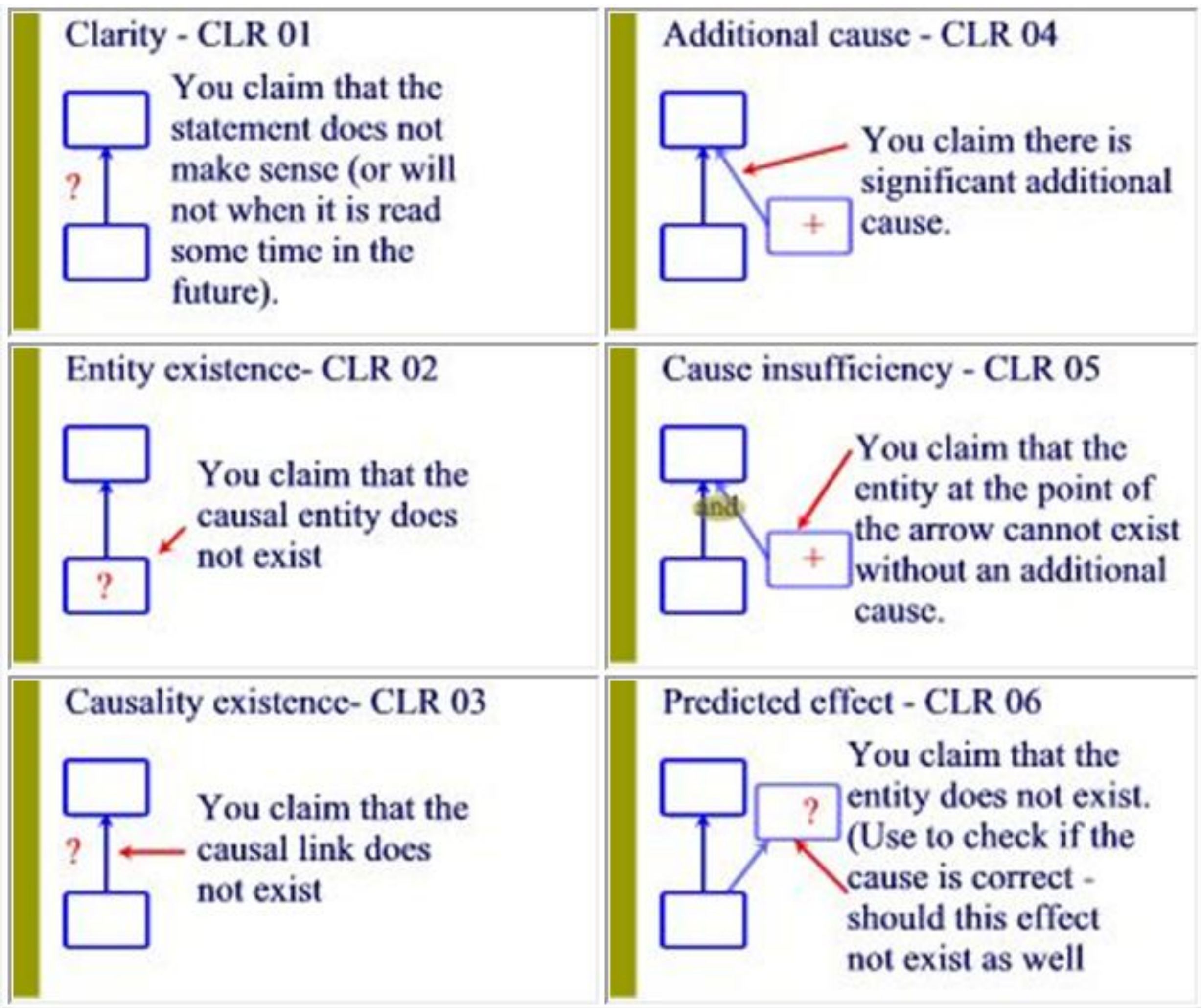


Figure III Graphical representation of CLR's (Goldratt-TOC Ltd., 2009)

To try every relationship established between factors or UDEs, the questions below are examples of how to test them in order to comply with the rigor of the tool.

1. Clarity: 'Would I feel compelled to add explanation if I were reading this to someone else?', 'I do not understand the entity/arrow…Could you explain further what you mean?' or 'Let me see if I understand. Is this what you mean?'

2. Entity Existence:
    a. Structure: Read the entity alone to ensure that it is a full statement
    b. Content: 'Does this entity, as expressed, really exist in the environment?'
3. Causality Existence:
    a. Structure: Read the arrow 'if… then…' and listen for partial statements.
    b. Content: 'Does the 'if… then…' really make sense in the environment?' and 'Is the cause why the effect exists or how we know it exists?'(e.g. 'House on Fire')
4. Cause Insufficiency: 'Does the effect always result when the cause exists, or only under certain circumstances?' (The 'certain circumstances' becomes another cause to be joined by an ellipse).
5. Additional Cause: 'Does the cause explain the magnitude of the effect in reality or are there other significant causes contributing as well?'

What tool do we use when we feel we need to really prove an answer to one of the questions above?

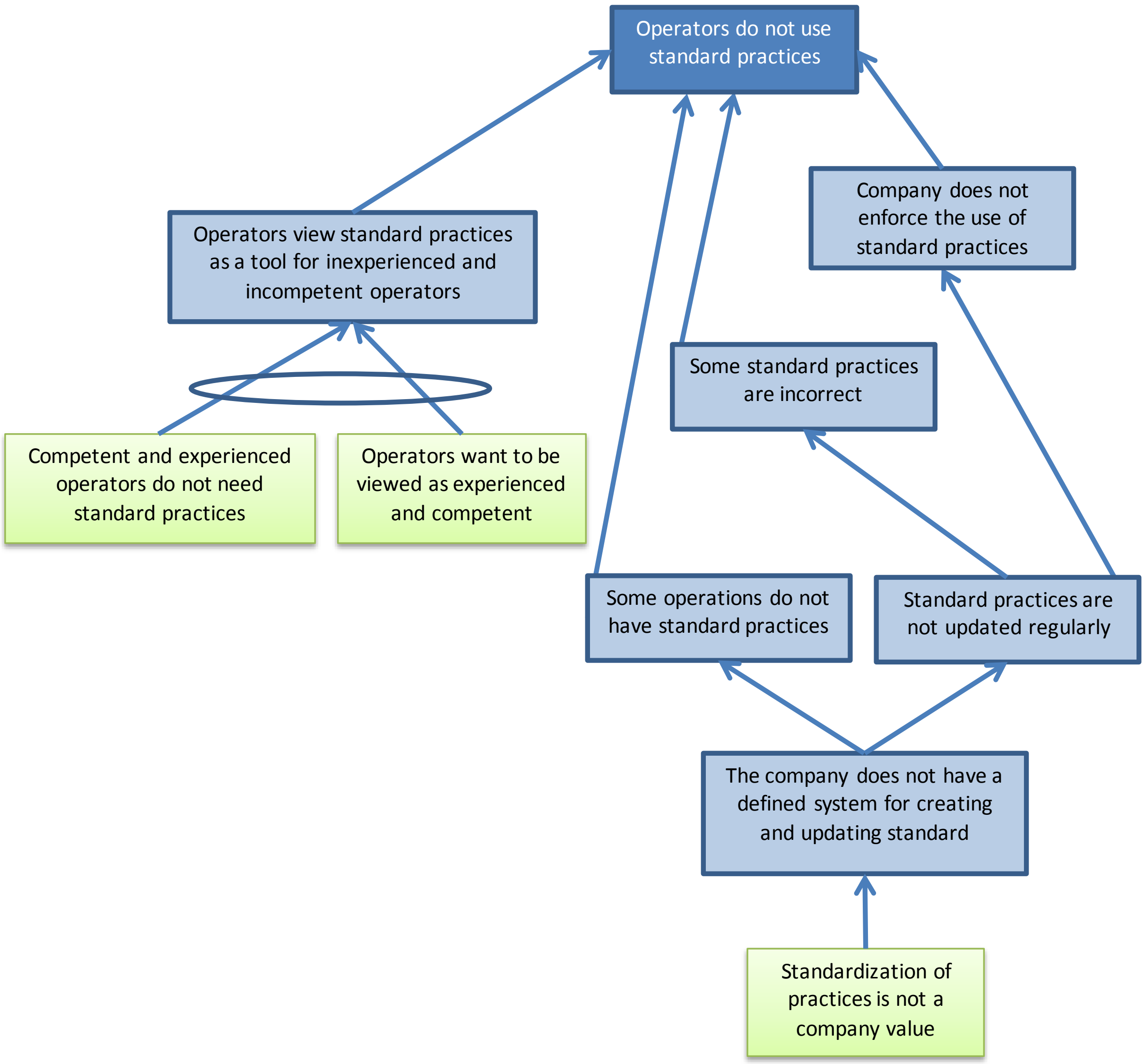
6. Predicted Effect:
    a. For Entity Existence: 'What effect would you expect to see if the entity did (or did not) exist?', and 'does it exist?'.
    b. For Causality Existence: 'If we got rid of (or increased) the cause, would there be a significant impact on the effect?'.

    'Using the same logic that exists behind the arrow, what other effect would you expect to see as an unavoidable result of the cause, and does it exist or not?'.

(Goldratt-TOC Ltd., 2009)

Example

Example taken from (Doggett, 2005).



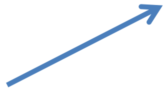
Root Cause:

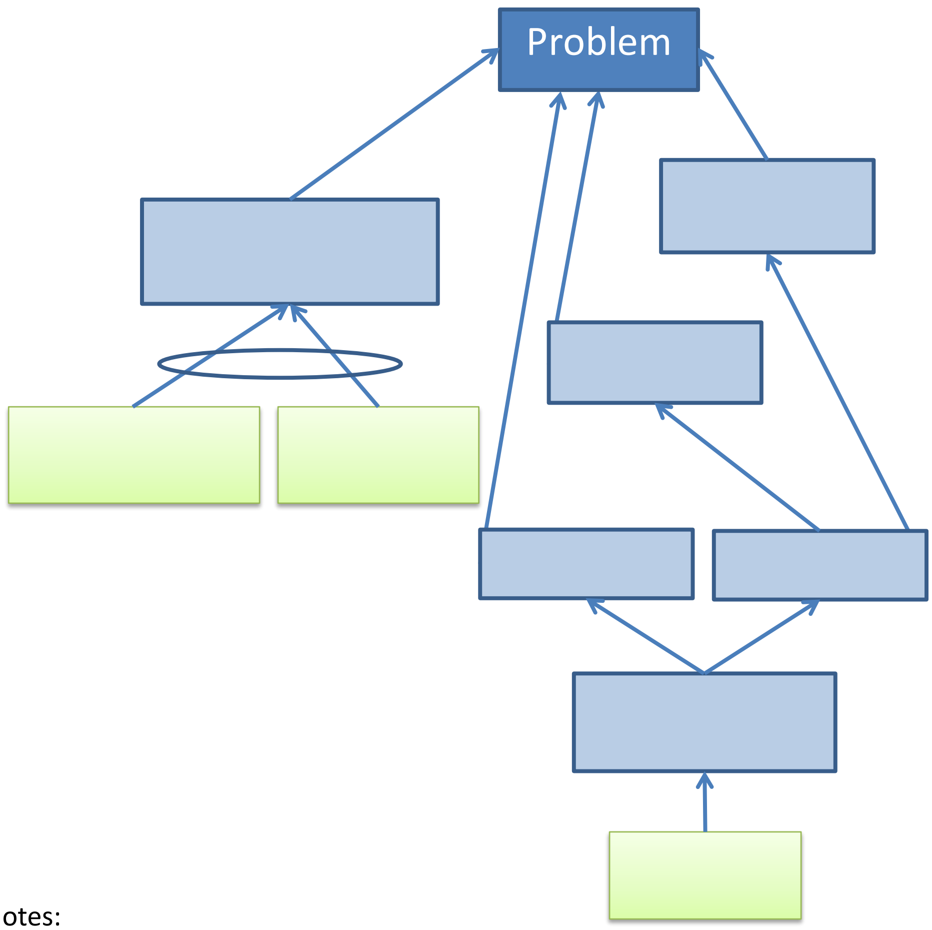
It has been found after analyzing the current reality for this problem, that the **Standardization of practices is not a company value**, which at the end **provokes to have lack on standardization practices** and that the organization does not enforce the use of them. Parallel to this, the **operators avoid the use of the standard practice** to **appear to be experienced and competent**.

Responsible(s) for solving problem:

1. Name: Checkpoint Date:
2. Name: Checkpoint Date:
3. Name: Checkpoint Date:

Template

Problem	Field to fill the main problem
Cause / Effect	Field to fill the causal factors for the effects listed. This causes can also be undesirable effects (UDEs)
Base (Root) Cause	Field to fill the deepest level causes found at each branch. This are most probably the root causes of the problem being analyzed
	Arrows signify a sufficiency relationship between the entities, implying that the cause is enough to create the effect
	The oval shows relationships between interdependent causes. It shows that multiple causes are contributive, so all of them have to be present for the effect to take place



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