



CC-Rail Guideline No.1, Rev.02

Risk & Opportunity Management

January 2022

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The Author

Andreas Heinzmann is one of the three initiators from the Alstom, Bombardier and Siemens system houses, who in April 2004 created what was then called the "Railway Industry Cooperation". Involving suppliers and operators, it evolved later into the IRIS Certification system of today. In May 2005 the IRIS Group elected Andreas as its first Chairman. After the successful launch of the IRIS in May 2006 he passed the reins in June 2007 to one of the co-initiators, Hubert de Blay (Alstom), but still remained active as an IRIS Steering Committee and IRIS Advisory Board member, co-editing for example, with Marcus Schmid (Voith), the IRIS Revision 02 in 2009. Together with Olivier Ringotte (Alstom), Sabrina Paeglow (Siemens), Emilio Sereni (Bombardier) and Angela de Heymer (UNIFE/IMC) he was also member of the core team in 2015 responsible for the draft of today's ISO/TS 22163:2017.



First with AEG-Westinghouse Berlin, and later with AEG in Hennigsdorf, Andreas became involved in a number of Rolling Stock projects (e.g. the Shanghai Metro, the Locomotive BR12X, and the Diesel Tilting Train VT 611/612). In 1998 he was appointed as the Head of Quality & Health Safety & Environment in Adtranz's "Light Rail Vehicles" Business Unit in Nuremberg. Even before the acquisition of Adtranz, he moved in 2000 to Bombardier (DWA) as General Manager for Quality & Customer Service. He subsequently worked 8 years at Bombardier Transportation's headquarters responsible for the worldwide development and implementation of the quality strategy. Through his professional experience spanning more than 39 years, he has got to know many suppliers and established a deep network of operators, approval authorities and registrars, not only in the rail domain but also in the automotive, aerospace and food industries. He has been working in a second capacity as lead auditor, trainer and consultant as far back as 1995. Andreas has a Masters in Electrical Engineering. Today he is one of the owners of International Competence Center Rail GmbH.

Barely anyone else has had such a decisive influence on the content of the IRIS standard and can provide insights on background information and give detailed interpretations.

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TABLE OF CONTENT

1 INTRODUCTION	4
2 PURPOSE.....	4
3 APPLICABLE DOCUMENTS	4
4 TERMS, DEFINITIONS; ABBREVIATIONS.....	4
5 RISK-BASED THINKING	6
6 RISK- AND OPPORTUNITY MANAGEMENT PROCESS.....	6
6.1 Risk identification / determination	7
6.2 Risk evaluation.....	7
6.3 Planning of actions for risk response	7
6.4 Monitoring of actions and regular updating of the risk analysis.....	7
6.5 Performance measurement of Risk Management (KPI).....	8
6.6 Learning from failures (knowledge management)	8
7 MANAGING BUSINESS RISKS	8
8 MANAGING PRODUCT RISKS	9
9 MANAGING PROJECT RISKS	9
10 MANAGING MANUFACTURING PROCESS RISKS.....	11
FEEDBACK	13
THANK YOU	13
ANNEX	13

Note: The numbers listed in this guideline (e.g.: 6.1.3-3) refer to the respective requirements in the IRIS Assessment Sheet.

1 INTRODUCTION

Risk & opportunity management is one of the substantial tasks of every employee. First of all however, top management, but also all process owners, project team members, design or industrial engineers must ask themselves whether they know their risks and how they want to get them under control. If risks have already occurred, then it's too late. Risks will always lead to financial losses (QDC) and can no longer be discarded from the books. Only opportunities that have been obtained could offset losses by savings. Therefore, a good risk & opportunity management is very much in the interest of a company to secure its economic success.

2 PURPOSE

The aim of this guideline is to assist companies in the implementation and maintenance of an IRIS-compliant business management system by providing guidance on the topics of risk & opportunity management and risk-based thinking. It is impossible to list all sections of ISO/TS 22163 that contain requirements in this respect. The IRIS Assessment Sheet alone mentions the term "risk" about 99 times. Risk management is a common thread that runs through many items of the standard. The core requirements are contained in Chapter 6.1.3 Actions to address risks and opportunities.

This guideline deals with the application of risk & opportunity management in the following four areas:

1. Business risks
2. Product risks
3. Project risks
4. Manufacturing process risks

The topic of risk-based thinking is of utmost importance especially for process owners.

3 APPLICABLE DOCUMENTS

Parallel to this guideline, the same topic is also presented in the appendix. Inside the guideline are several cross-references referring to images recognizable by the screen symbol displaying the corresponding page numbers.

4 TERMS, DEFINITIONS; ABBREVIATIONS

The terms, definitions and abbreviations used in ISO 9000 and IRIS shall apply to this guideline insofar as they can be found there.

Preventive action:

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation:

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Mitigation action:

Action to mitigate or limit the impact, severity or intensity of a risk incurred.

NOTE 1 Neither ISO 9000 nor IRIS contain definitions of this term. Therefore, the term was derived by me.



Correction:

Action to eliminate a detected nonconformity.

NOTE 1 A correction can be made in conjunction with a corrective action.

NOTE 2 A correction can be, for example, rework or regrade.

Corrective action:

Action to eliminate the cause of a detected nonconformity or other undesirable situation.

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action.

Risk provision:

Cost item due to risks that is shown in a calculation or balance sheet as an expected sum but still is uncertain regarding its occurrence, amount or due date.

NOTE 1 I derived this term as neither ISO 9000 nor IRIS contain definitions of this term.

Quality Deficiency Cost (QDC):

Additional costs resulting from nonconforming products, processes or equipment.

NOTE 1 QDC can be distinguished by causer (e. g. sales, engineering, production, purchasing, project management) and on phase of occurrence (e. g. tender, design, production, post-delivery).

NOTE 2 QDC can include:

- a) additional labour, material or other direct costs in the context of failure or change due to incorrect design and the resulting actions taken (e. g. rework, redesign, repurchase, special shipments);*
- b) costs due to downtimes;*
- c) costs of scrap;*
- d) costs of products rendered unusable by or oversupply of storage;*
- e) costs due to accepted third-party claims and costs due to claims not asserted by the organization against third parties;*
- f) costs due to penalties for default or delays.*

Note 3 QDC can also be called nonconformity costs.

FMEA (Failure Mode and Effects Analysis):

Method for early risk identification and avoidance.

SIPOC (Supplier-Input-Process-Output-Customer):

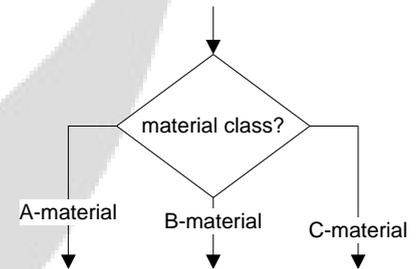
Method for process representation.

5 RISK-BASED THINKING

Risk-based thinking often happens unconsciously. For example, who would come up with the idea and plan a First Article Inspection at the manufacturer site for new standard material such as screws, nuts, washers? Probably nobody, although your First Article Inspection process for new purchased parts mandatorily prescribes it. The question is when can we take shortcuts in our business processes, and when do we have to handle the full program? Who determines this? When is this allowed and where are the criteria described?

Probably every company uses different material classes (e.g. A-, B- and C-parts). This classification is based, almost without exception, on risk-based thinking, since you classify the material, consciously or unconsciously, by means of a risk assessment. The applicable criteria must be defined clearly and comprehensibly for each user (in a controlled document), so that the result is traceable, and everyone can undoubtedly come to the same conclusion.

A classification allows us to incorporate branches into our business processes in order to follow different process routes. Risk-based thinking has the purpose of determining the necessary type and extent of controls that affect a process, product or service. Therefore, please pay attention to the formulation in 6.1.3-3 of the IRIS assessment sheet. If you read there "... *type and extent of controls* ...", then you always know that you must classify. This applies five times particularly to:



1. 6.1.3-3 (general),
2. 8.1.2-2 (tenders),
3. 8.1.3-2 (projects),
4. 8.4.1.1.1-1 (external provider and
5. 8.4.1.1.1-1 (external provided products, processes or services),



But of course, the application is not limited to these matters. Please read also:

Conclusion: risk-based thinking gives us the opportunity to model our processes as we deem appropriate and necessary. However, we must never forget to document, train, use and maintain our classification schemes and to incorporate the right "switch points" in our business processes.

6 RISK- AND OPPORTUNITY MANAGEMENT PROCESS

I transformed the ISO/TS 22163-requirements into a flow chart. Please go to:



You can go through the process once under the aspect of risk assessment, and then through the same process again under the sign of opportunities. The process itself does not differ, but the applicable methods may. In this guideline I will mainly deal with the topic of RISK.

6.1 Risk identification / determination

First of all, it is recommended to carry out a stakeholder analysis, depending on the problem, in order to get the right people around the table. Customers or suppliers might be considered as well. In this phase, brainstorming is often used as a methodical approach (unlimited collection of spontaneous ideas). In order to stay on track, a well-structured risk repository (e.g. a risk checklist, which contains all the things that went wrong with the same subject in the past) should be used and, of course, the documentation of the risk object under examination (e.g. contracts, requirement specifications, functional specifications, drawings, etc.) should not be missing. As a result, you will determine many potential failure possibilities to be filtered in a next step.

IMPORTANT! Carry out a risk analysis always at the beginning of a process. Otherwise, the time at which risks could still be avoided may already have passed.



For example, you start a FMEA-project already in the tendering process so as to initiate even more effective countermeasures than later, when the order is already in-house.

6.2 Risk evaluation

By choosing the FMEA methodology, you will be well guided alone by the tool (form or program). If you have many statistics, data and facts at your hands, you can closely estimate the probability of occurrence, the severity of a failure and the probability of detection (e.g. on a scale from 1 to 10). Define the thresholds above which you must start to take preventive and mitigation actions (mandatory) or could start (optional). It becomes problematic if you have, unfortunately, only a very limited amount of statistical data available. Then you must roughly estimate the probabilities. You will find an example in the annex.



6.3 Planning of actions for risk response

Basically, you first look for actions that could eliminate a risk. If you can't think of anything, then look for ways to prevent it. Preventive actions are directed towards the causes of occurrence or the improvement of probability of detection. In addition, you are still thinking about mitigation actions (risk limitation to reduce the severity or extent of damage) and/or a possible risk transfer (e.g. insurance). In the end, there will often be a risk left despite all conceivable actions, which you must accept, and therefore, you may have to set aside a risk provision.



6.4 Monitoring of actions and regular updating of the risk analysis

As with any other action plan, the realization of the planned activities must be monitored and reported. You yourself determine how often this should happen (e.g. every 2 weeks, every month, every quarter).

However, it is important to understand that new risks can arise all the time or that some risks that have already been identified can no longer occur. Therefore, the risk analysis must be regularly repeated and updated. Here too, you decide yourself when this should happen. You can either mark this in your calendar or link the points in time to events in the process flow (e.g. before each gate).

6.5 Performance measurement of Risk Management (KPI)

I've mentioned it before. Whenever risks occur, financial disadvantages (unplanned additional costs) must be accepted. Either the financial damage occurs even though you have recognized the risks, but unfortunately, all countermeasures were not effective.



Or you didn't recognize the risks and yet they still appear surprisingly out of the blue. The effects do not differ. This always results in consequential failure costs (QDC), which you should collect, analyse and avoid in other or subsequent cases. Therefore, the costs resulting from non-conformities (QDC) are the direct measure of the process performance of risk management (a mandatory KPI). The better you get your risks under control, the lower your QDC will be. Or vice versa: The best way to avoid QDC is to introduce an effective risk management!

Note: However, it is of the utmost important that you measure QDC in its full scope according to its definition. Otherwise you will miss out on the enormous benefits of this KPI.

6.6 Learning from failures (knowledge management)

Long ago my COO told me, "if mistakes happen, it's human error. But mistakes just mustn't happen again." That's what it's all about. You must learn lessons in order to be able to respond to the risk better next time. Not "what didn't work" is of interest only. Also "what did work well" must be remembered correctly. It is best to continuously fill a risk repository, or at least a risk checklist, which helps you to identify and avoid risks better the next time (see 6.1).

7 MANAGING BUSINESS RISKS

I refer to chapter 6.1.4 of the standard. For legal reasons, it is prohibited to reproduce the requirements here. Therefore, please read the requirements in your copy of ISO/TS 22163.

This requirement implies that contingency plans must be established systematically and structured based on regular business risk analysis. This means: thoroughly execute the risk management process for the business planning, but you are free to choose the method. Since we talk about business risks, the responsibility for this task is almost self-explanatory. In my opinion, one of the most important tasks of the executive board is to prevent risks from harming the company. For this purpose, I recommend identifying the risk fields and assigning a "caretaker" to each field. As a rule, these should be board members who jointly act according to a previously agreed risk evaluation method. For example, the following risk fields might be assigned:

- IT Infrastructure risks Head of IT (disaster recovery plan)
- HSE risks Head of occupational health & safety (hazard analysis)
- Site risks Head of Production (analysis of critical machineries)
- Currency risks Head of Finance (hedge planning)
- HR risks Head of Human Resources (succession planning)
- etc.

Contingency plans can be prepared on a decentralized basis but must be harmonized with each other prior to release. Managers should always keep an eye on all local risk situations (the examples given in Note 1 of the norm alone are not enough!) and update the plan at least once a year, e.g. as part of the strategic business planning cycle.

8 MANAGING PRODUCT RISKS

Product FMEAs are only indirectly required in the IRIS standard by the reference to the following applicable IEC standards in Section 8.8 (RAMS/LCC):

- IEC 62278 or equivalent, applicable for RAMS activities
- IEC 62425 or equivalent, applicable for safety-related electronic systems;
- IEC 61508 and IEC 62425 or equivalent, applicable for safety-related Electrical/Electronic/Programmable Electronic products or services;
- IEC 62279 or equivalent, applicable for safety-related software

Specific requirements for a particular product group result from the above-mentioned standards and from the product approval regulations (e.g. TSI standards).

Product FMEAs are useful, for example in the case of:

- significant new development (e.g. new platform product),
- design with significant changes / modifications,
- new or significantly modified production requirements,
- problems with similar parts in the past,
- new materials or parts,
- particular safety aspects (see IEC standards) always!
- high complexity regarding functional or integration requirements.

At this point I would like to refer to the [IRIS Guideline No. 4:2016 "RAMS / LCC"](#) (download) as well as to our 4-day [RAM/LCC seminars](#) (link) which is a thorough training on how to manage product risks.

9 MANAGING PROJECT RISKS

The requirements regarding project risks can be found in Section 8.1.3.8: Project risk and opportunity management. For legal reasons, it is prohibited to reproduce the requirements here. Therefore please read the requirements in your copy of ISO/TS 22163.

What is often unclear or misinterpreted is the financial analysis of risks and opportunities required under point b). If you take a closer look and remember that this requirement originally stems from the PM Book of Knowledge published by the Project Management Institute, then



you would better understand in case you as a PMI-certified project manager or are otherwise well versed in the field of project management.

In a nutshell, it is a monetary evaluated risk analysis that alternatively considers a different risk priority in the form of money, instead of the commonly used risk priority number:

- the probable damage (amount of loss) in EUR, USD CNY or other applicable currencies.

With this method, each risk initiates a detailed cost-benefit analysis. I refer to the example "the warehouse" in the annex and try to explain this methodology:



Suppose the warehouse has a time value of 100,000 EUR and the probability of the warehouse catching fire is 50%. Then the probable damage (amount of loss) would be 50% x 100,000 EUR = 50,000 EUR.

What could be done to reduce the probability of occurrence? Due to this question, all mitigation actions are immediately omitted, as they would only influence the impact (severity). All that remains are avoidance, preventive actions and transfer, as in this example:

Hypothesis: The warehouse is empty and the actual value of the warehouse building is currently 100 TEUR, not considering the inventory stock (0 TEUR) nor the value of a life, even if it's a smoker :).

	WHAT risk do you see (brainstorming)?	before action			after action					re-assessment: would you take this action?
		max. damage in TEUR, if the risk occurs (severity)	initial probability of occurrence (%)	initial risk in TEUR	proposed actions	type of action	budget for action (in TEUR)	probability of occurrence (%) when action is done and effective	remaining risk (in TEUR)	
1	the warehouse burns down	100	50%	50	Smoking ban	prevention	0	45%	45	yes, sure!
2				45	Decommissioning of the warehouse and relocation to a rented warehouse	avoidance	15 TEUR per annum = 150 TEUR	1%	0,45	no, too expensive for subsequent years!
3				45	Signing a fire insurance contract without modernization	transfer	10 TEUR per annum = 100 TEUR	50%	0	no, too expensive for subsequent years!
4				45	Modernization of gas- and electrical installations and conclusion of a maintenance contract	prevention	25 TEUR plus 1 TEUR per annum	1%	0,45	yes
5				0,45	Signing a fire insurance contract (after modernization)	transfer	1 TEUR per annum	1%	0	yes, maybe, could be done

Conclusion: in this example, the smoking ban and the modernization measures would be implemented. The costs (investments) would be 25 TEUR plus 1 TEUR annual recurring costs. Hence, the initial risk of the warehouse burning down would drop to an acceptable 450 EUR for at least 10 years. If you want to make it completely safe (remaining risk = 0 TEUR), you could sign a fire insurance (line 5). However, the annual premium would be higher than the initial risk.

This trivial example alone tells you what it is all about: a cost-benefit analysis for each individual risk. The more expert judgement you gather and the longer your field experience, the better your analysis, including possible risk reduction strategies, will be.

The standard requires the application of this methodology already in the tender phase (see 8.1.2-2 c). This makes a lot of sense because after the monetary evaluation of all commercial, contractual and technical risks of an inquiry, the costs of the actions can be incorporated into the bid calculation scheme using this method, as well as the level of remaining risks as risk provisions. In this case, the risk provisions would provide the permitted framework for the QDC of a future customer contract, i.e. a kind of "budget" or maximum value for the quality deficiency costs, which should not be exceeded by the project in the event of an order. Otherwise, this would lead to a direct reduction in profits and, in the worst case, would end up bringing project balance sheet into the red.

I hope that I have been able to explain this method in a reasonably plausible way. You will no doubt still have a lot of questions. Here I can only invite you to one of my seminars [Internal IRIS Auditor](#) (link) or [IRIS Project Manager](#) (link). There I dedicate several hours alone on this matter to discuss it in much more detail and to play through an extensive case study which will deepen your understanding even more. There you will get also the appropriate FMEA project template, including the correct solutions.

Now a few words about opportunity management in the project. Look at it from the opposite perspective and ask yourself: "What can I do to gain financial improvements (e.g. savings, higher sales, improved margins, etc.)? Here too, you must first collect ideas in a team, evaluate/filter them and then plan actions to implement the best ideas. This will also cost a price (budget), and in the end financial improvements must be proven (e.g. savings/budget cuts, higher profits, more cash/less interest). So, you follow exactly the same process and can also use the FMEA project form with slight modifications.

Good project managers always keep an eye on the opportunities. Because you know that risks can never be avoided 100% and that they have only a few possibilities to compensate for the resulting losses, often only through realized opportunities (savings). If the project results should not show a continuous downward trend, then you must realize opportunities to take countermeasures.

Summary:

The monetary-weighted project FMEA begins in the tender phase (initial FMEA) in order to determine the budgets for the risk response and risk provisions. It requires regular updates, for example monthly, or once per project phase, and is continued until the end of the project life.

10 MANAGING MANUFACTURING PROCESS RISKS

Please read Section 8.3.1.1-2 (Design and development of products and services - General - Supplemental) and Section 8.5.1.2-2 (Special processes) in your IRIS Assessment Sheet. For legal reasons, the requirements may not be reproduced here.

Manufacturing FMEA-processes make sense in case of:

- significant new technologies in production,
- production process with significant changes / modifications,
- problems with similar production processes in the past,
- production of new products or new parts assembly,
- processes with particular safety aspects,
- special processes (gluing, crimping, soldering, plating, etc.),
- automatic or semi-automatic processes with high complexity,
- outsourced processes with high impact on product quality or safety,

- being required by customer or standards.

The interpretation of the requirements in Section 8.5.1.2-2 should be consistently such that a risk assessment is provided for every existing special process. Ideally, this would be presented in the form of a FMEA process that was created before the commissioning of that process in order to plan timely actions for failure prevention, damage mitigation and/or improvement of detectability in the subsequent process development.

In the annex on pages 35-42 you will find an example of a FMEA process.

The development of a SIPOC seems to me to be indispensable. In this example, this table contains all the essential risk fields of the colouring process and later provides an excellent structure for the risk assessment. Line by line, you work your way systematically through the table and ask:



- What can happen to the input variables?
- What can go wrong with the identified critical functions / parameters?

Without this systematics and structure, one could quickly lose track of the situation and perhaps overlook essential risks.

I am sure you have noticed that in this guideline I have focused on the mandatory requirements of ISO/TS 22163 only. Including all optional requirements of the IRIS Assessment Sheet would have quickly doubled the number of pages. Come to our course [IRIS Project Management](#) (Link) if you want to learn more about this topic.

- - End of the guideline -

FEEDBACK

In case you do not agree with the content, please let me know your opinion. Nobody is perfect and we all make mistakes. If you have the better arguments, I will adapt / correct this document together with you.

You can find the actual edition of the guideline on our webpage <https://www.cc-rail.info/en/> under ABOUT US/DOWNLOADS (<https://www.cc-rail.info/en/assets/>).

THANK YOU

I would like to thank André Hasler and Xiuluan Shi very much for always providing me with their advice and support and their critical opinions. Both gave me the idea to write this guide. My thanks go out to both of them for this!

I would also like to thank Simon Kenyon, who once again succeeded in making my English more readable and understandable.

For the correctness of the Chinese translation I trust, as always, my business partner Xiuluan Shi.

ANNEX

Presentation "risk and opportunity management" (excerpts from various training documents)



Welcome to the „HIGH SCHOOL“

Risk and Opportunity Management

(according to the requirements of ISO/TS 22163)

Excerpts from our training documents:

1. Internal IRIS Auditor
2. Supplier Performance Management
3. RAM/LCC
4. IRIS Project Management

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0.3.3 Risk based thinking

... is used to determine the type and extent of controls that apply to a process, product or service.

➤ Question:

Is it really necessary to manage all external provided products or services and all external provider with the same care?

Implementation of risk based thinking

(best practices part 1: material classification)



classification of external provided products

RISK		functional requirements	degree of innovation	manufacturing technology	Availability at the market (Obsolescence)	Supplier region	Score
Rank	Points	30%	25%	25%	15%	5%	7,50
HIGH	10	Increased functional requirements / features Safety-related material or material with serial numbers Specification / tender documents and / or 3.1 certificate required	10 New product development (significant changes in technology are required; supplier has no experiences with the new technology)	10 Complicated production technology with many special processes, Manufacturing processes with an increased failure rate	Less than 5 years on the market	outside of Europe	> 6.7 - 10
MEDIUM	5	Average number of functional features, no specification / specification required, e.g. Order by drawing	Product development is given, but modifications are necessary	5 Manufacturing process with adjustments Manufacturing processes with medium failure	5-7 years yet available	5 Europe	> 4.2 - 6.7
LOW	0	Standard Material	proven product, no modifications necessary	known process without significant adjustments No Q-problems in the past	Material is fully available	your country	0 - 4.2

Only 2 obvious implications of such material classification:

- impact on parts approval process



e.g. A-Parts may require FAI, while C-Parts can be handled as Kanban

- impact on specifications



e.g. A-Parts may require GRD&TRD , while C-Parts can be ordered with catalog number

Risk based thinking

Implementation of risk based thinking

(best practices part 2: supplier classification)

classification of external provider

logical OR operation					Supplier Class
Material-class	Order Volume/year	Scope of supplier	approvals & certificates	Dependence on Supplier	
A	> 100.000	Development and production by the supplier	Special approvals required for manufacturing, eg Welding (EN 15085), adhesion (DIN 6701), soldering, casting, etc.	Single Source to establish a second supplier it needs high invest	A
B or C	50.000 - 100.000	only production by the supplier	no Q-history, a new supplier	Change of supplier with cost / expenses	B
B or C	< 50.000	Purchasing via dealer / trader	no approvals & certificates	2nd or 3rd backup supplier is available, it's simple to change the supplier	C

Implications of supplier classification:

- impact on supplier approval



e.g. approval of new A-Supplier requires full SEAP, while new C-Vendors can be approved based on a filled supplier data sheet only

- impact on supplier evaluation



e.g. A-Supplier get performance objectives and regular feedback, while C-Supplier can be “ignored”

Risk based thinking

Is it really necessary to treat all customer with the same care to make them happy?

Is it really necessary to manage all tender with the same care to win orders?

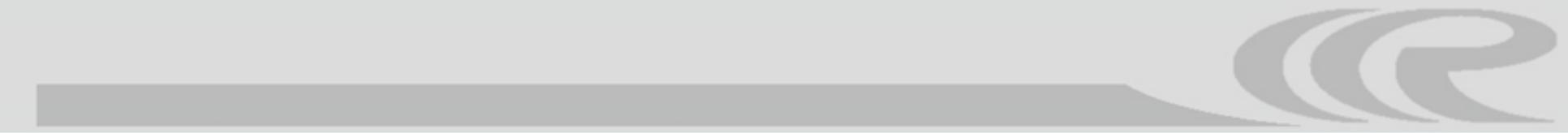
Is it really necessary to verify all incoming goods with the same care to ensure availability of materials in production?

Is it really necessary to test & inspect all work in progress with the same care to ensure defect free products?

Is it really necessary to order 3.1 Certificates (EN10204) for all external provided products?

Is it really necessary to verify all 3.1 Certificates (EN10204) of raw materials by own lab-tests on a quarterly basis?

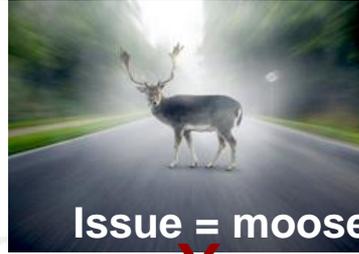
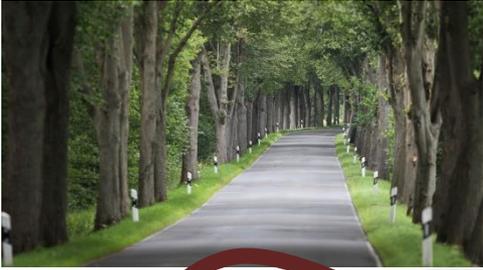
.....



Planning

6.1 Actions to address risks and opportunities

Definitions



country road



t +1 containment action
= immediate action to correct

t +2 corrective action
= action to eliminate the root cause in order it doesn't happen again

t -1 preventive action

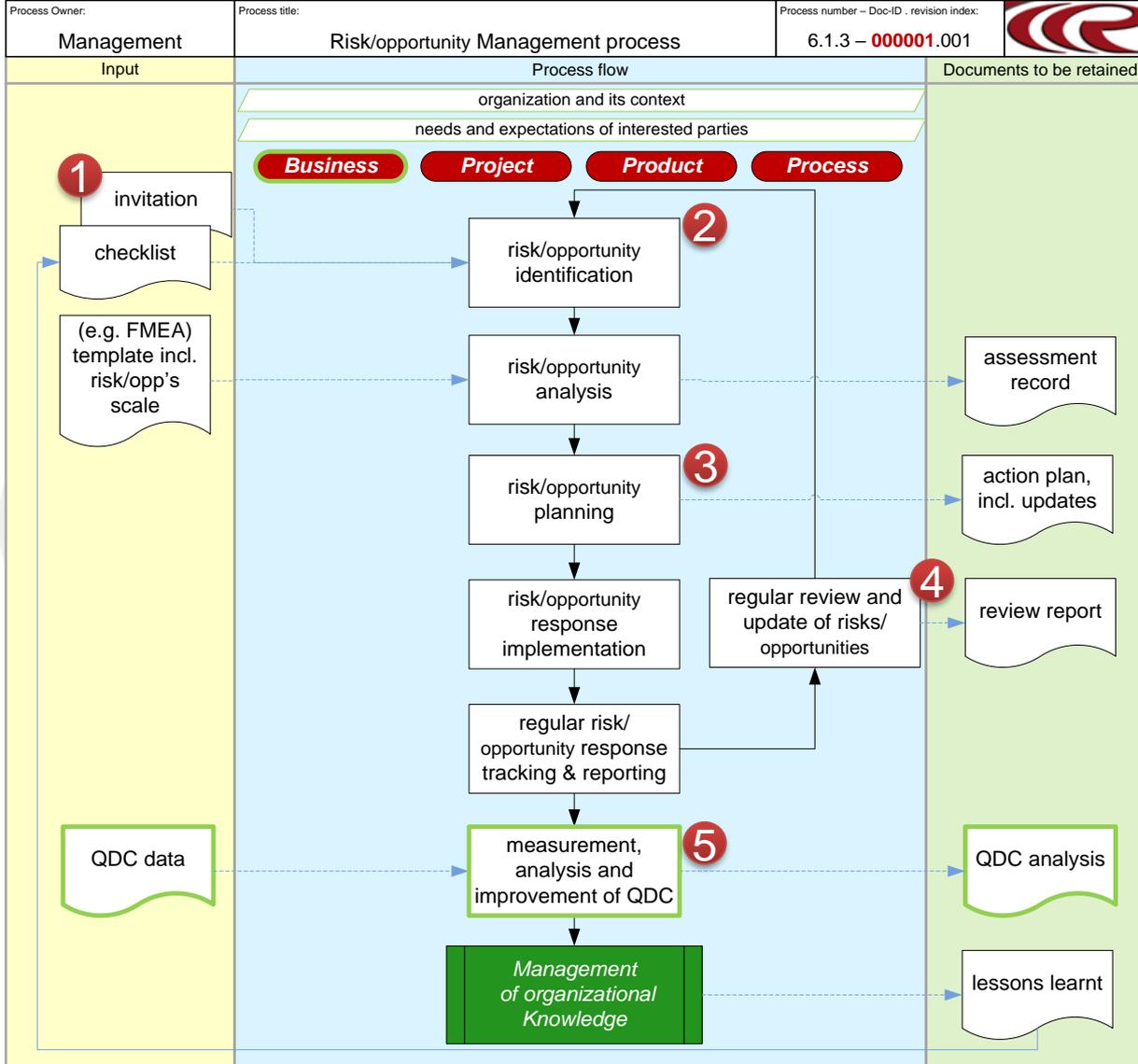
= action to eliminate the root cause of a potential issue in order it doesn't happen

t -1 mitigation action

= action to reduce the impact/damage when the risk occurs



Risk & Opportunity Management



1 *involve customer and external providers in joint work on risk assessment and response.*

2 Determine the risks and opportunities that need to be addressed to:

- give assurance that the business management system can achieve its intended result(s);
- enhance desirable effects;
- prevent, or reduce, undesired effects;
- achieve improvement.

3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

The organization shall plan:

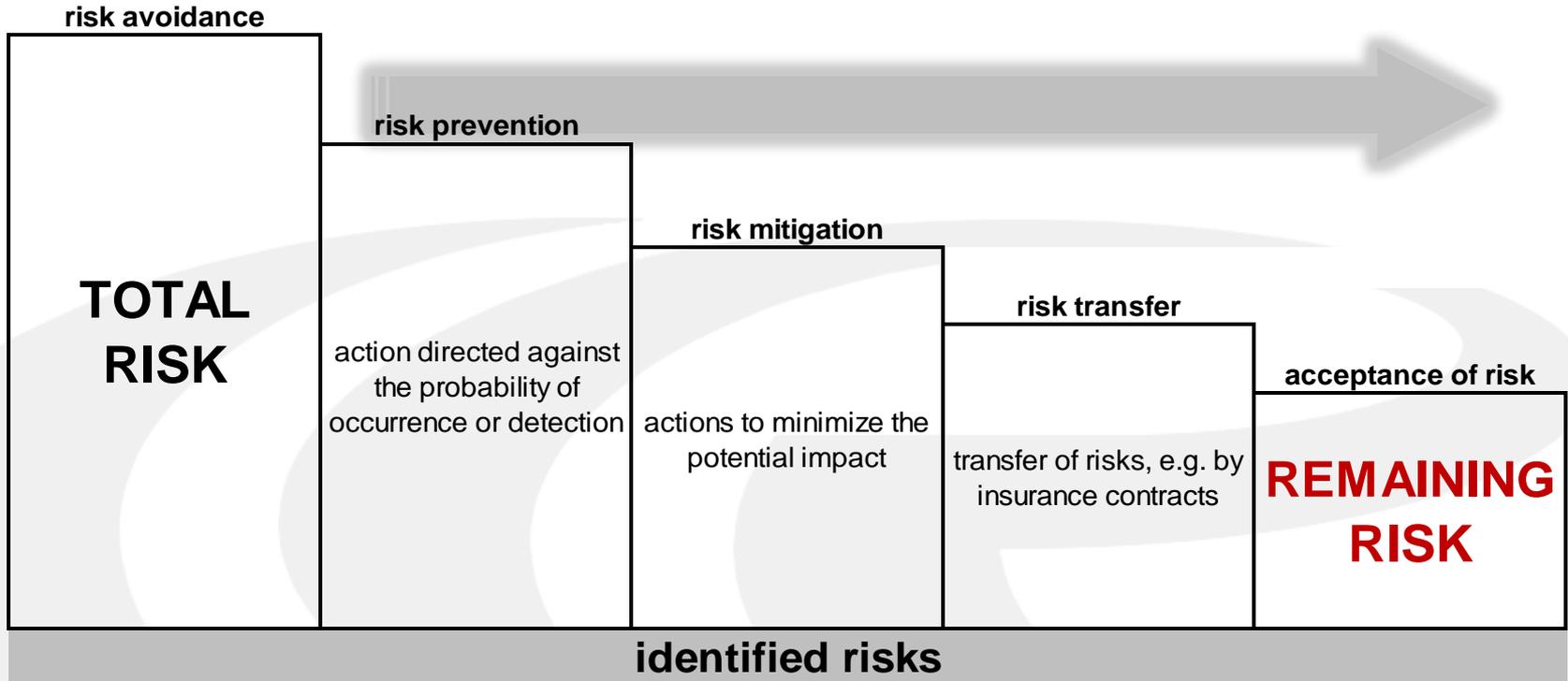
- actions to address these risks and opportunities;
- how to:
 - 1) integrate and implement the actions into its quality management system processes,
 - 2) evaluate the effectiveness of these actions.
- define criteria to determine the type and extent of controls in its processes

4 *multidisciplinary approach for risk reviews*

5 evaluate the effectiveness of risk management *based on QDCs*

Chapter 6.1.3

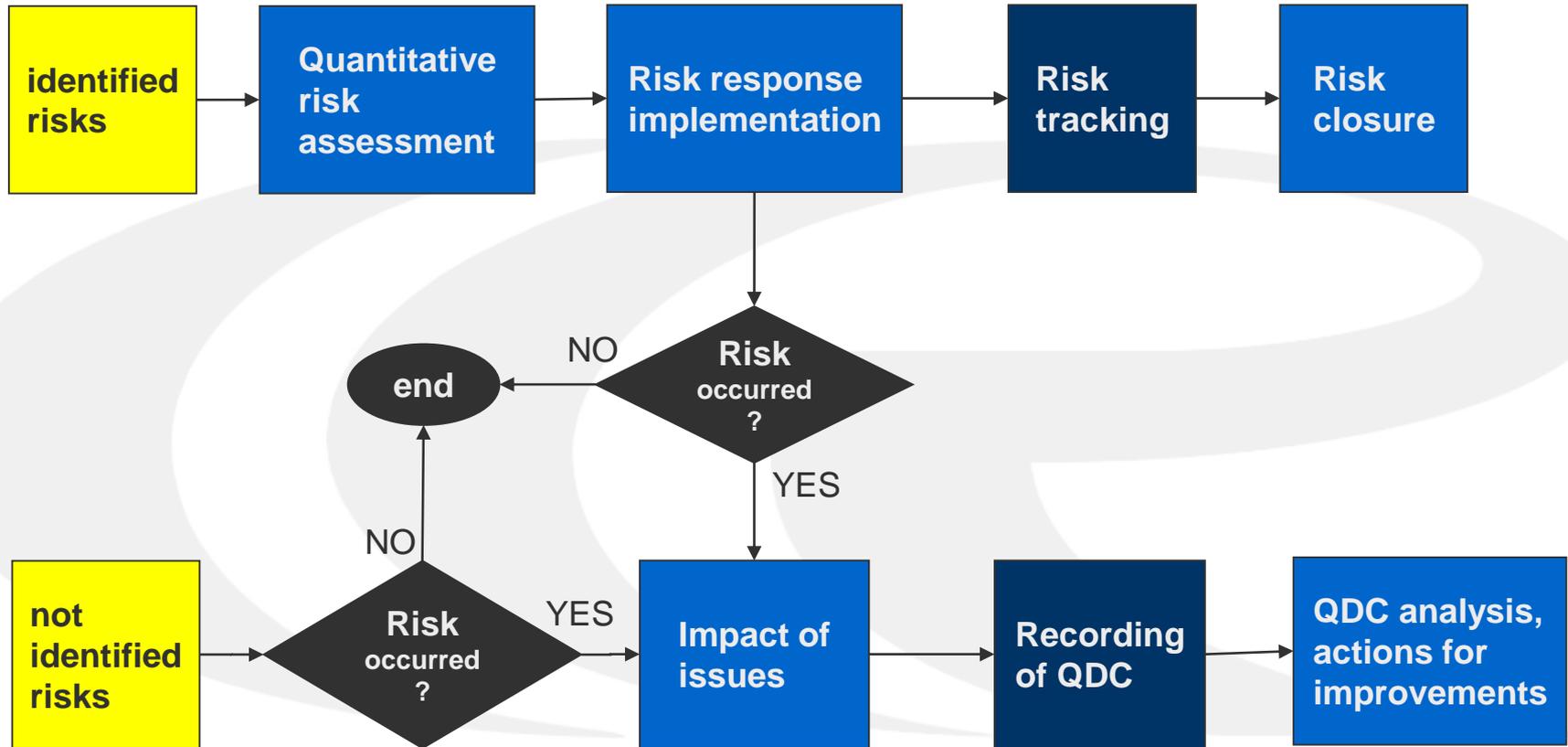
Planning of risk responses



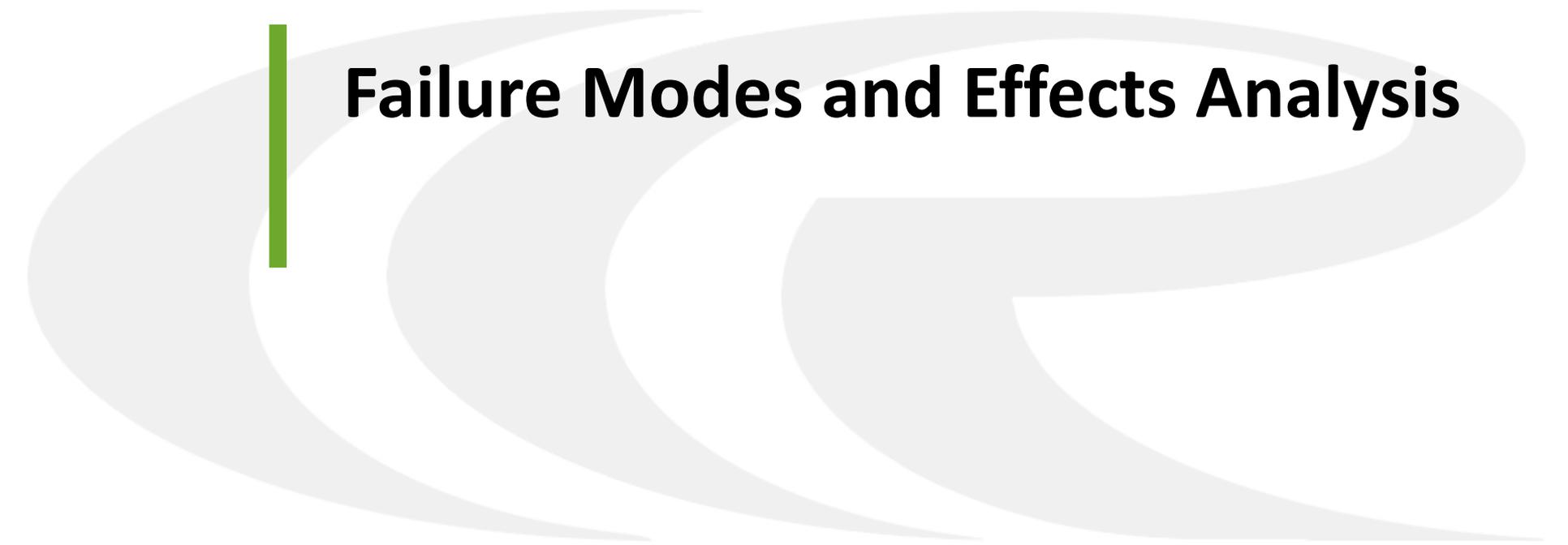
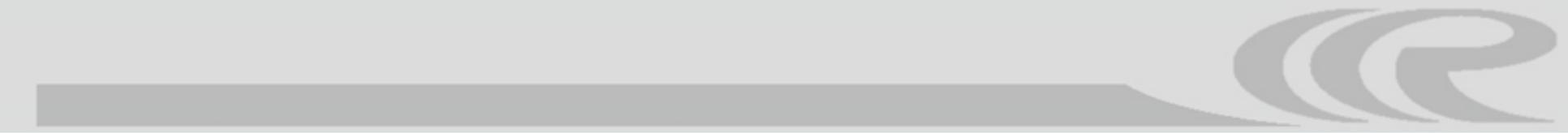
target:	exclude risk	prevention of the causes of occurrence or improve the possibility for detection	reduction or limitation of the damage	minimizing the consequences of the damage	hope for the best and prepare for the worst constitute risk provisions
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PREVENTIVE	REACTIVE		

Chapter 6.1.3

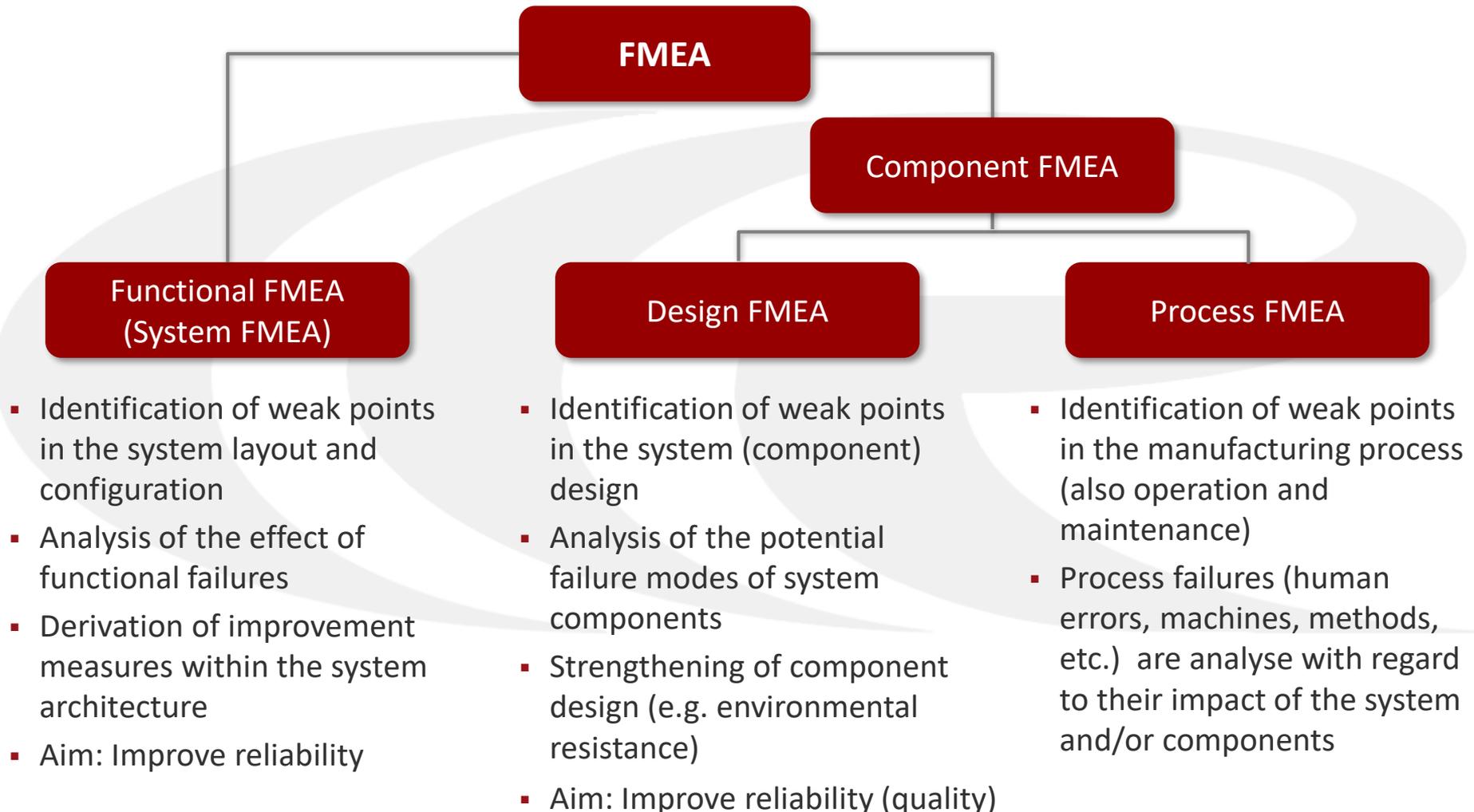


AH: "I'm convinced that Quality Management is profoundly logical. It's basically all about getting the risks under control."



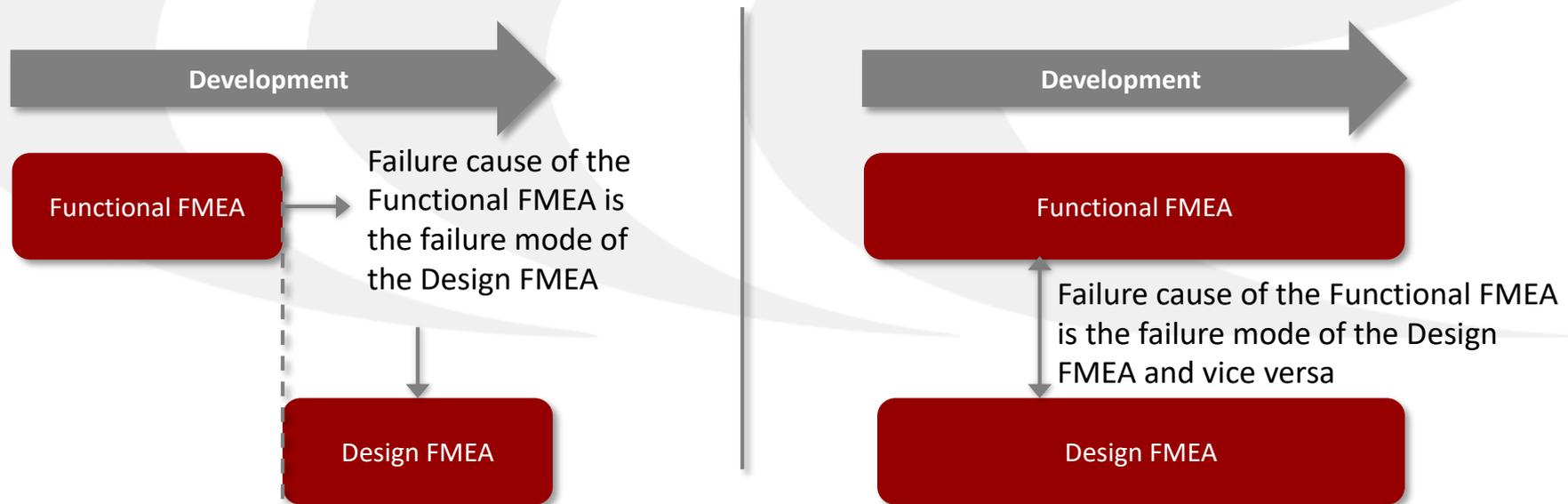
Failure Modes and Effects Analysis

Versions of the FMEA



Versions of the FMEA and systematic procedure

- Conservative approach
 - Functional FMEA is the basis for the design FMEA
 - All different types of FMEA analysis are performed independently as a sequence and by different people
- A modern approach requires a simultaneous and continuous processing



Planning

6.1. Business Risk and

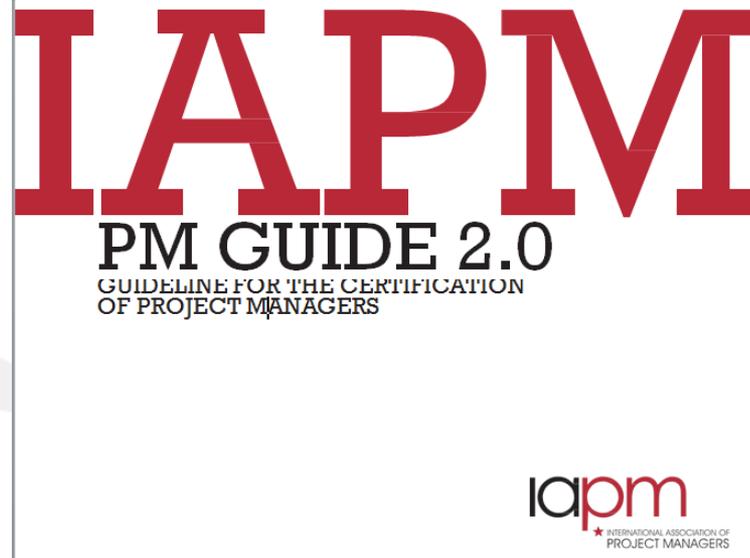
6.1.4 Contingency Planning

Establish, validate, where applicable, and regularly review a contingency plan based on an evaluation of business risks, such as utility interruptions, interruptions in the supply chain, labor shortages, critical technologies, key production equipment failure, field returns, succession plan, information and communication technology and much more...

Are you aware about our
**Project Management
master class?**
(www.cc-rail.info/en/004-2/)

Project Risk

recommended lecture:



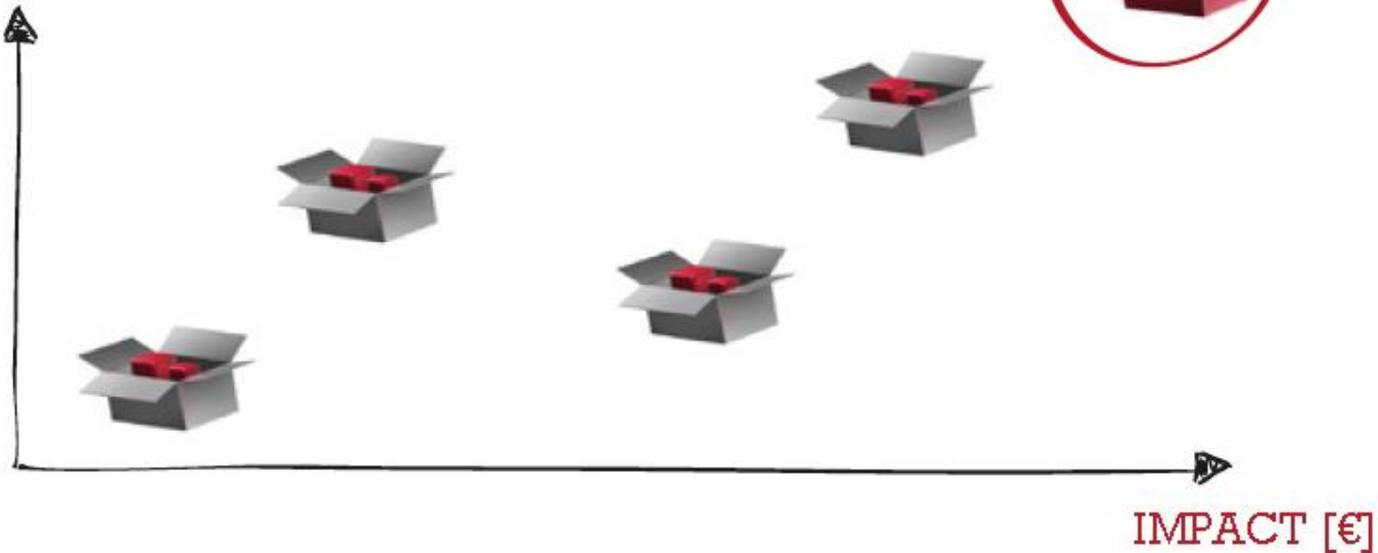
http://www.cc-rail.info/wp-content/uploads/2016/10/iapm_pm-guide2_en.pdf

Monetary weighted RISK ANALYSIS

monetary evaluation of risks:

Chart

PROBABILITY OF OCCURRENCE [%]



fields of risks:



One risk may have an impact / influence on other risks.

1) Risks due to stakeholders

(resource):

- There is a risk of external influences due to non-project relevant reasons (political, personal, power-related ...)
- There is a risk that there are problems with internal or external staff (expertise, availability, motivation ...).

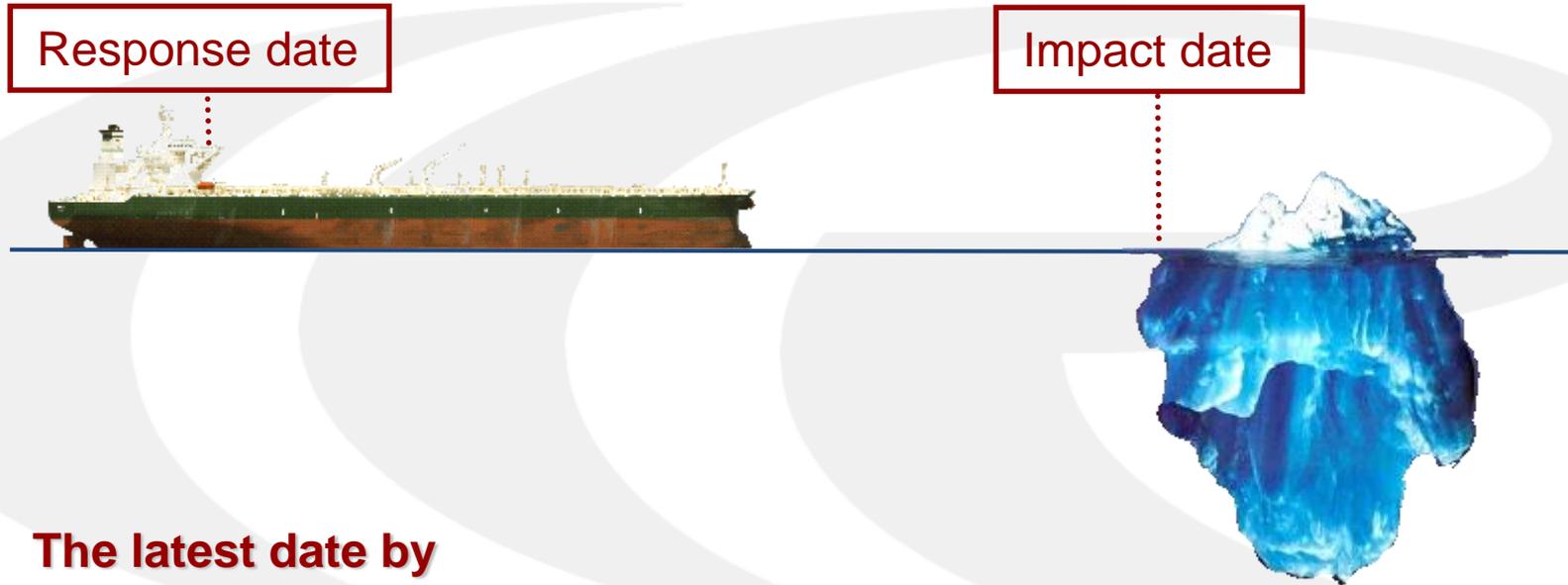
2) Risk of confusion, changes in goals or inadequate conditions :

- There is a risk that unwanted / not accepted results are achieved.
- There is a risk a project fails due to a lack of resources or support.

3) Risk through lack of information:

- There is a risk that things are not considered due to a poorly managed project file or that they will be processed in parallel or re-invented.

Consider the response date!



The latest date by which we must do something.

Example: Define and Mitigate

Risk: our old warehouse building

Define clearly and concisely

There is a risk that your warehouse will catch fire, the risk is caused by very old gas works and electrical works in the house. Also you smoke 60 cigarettes a day! The direct impact of the risk occurring will be the house burning down.

“3Cs” = Condition,
Cause and
Consequence

Reduce risks effective and efficient

Do you have ideas / suggestions?

I already ask for 2 offers:

modernization of gas:
best offer: 15 T EUR

modernization of
Electric:
best offer: 10 T EUR

Does the action target:

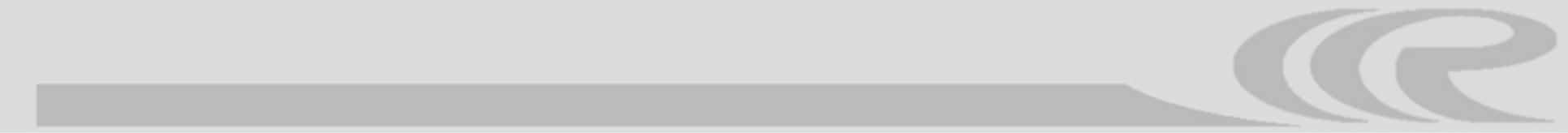


Transfer the Risk?

Target the Risk Cause?

Reduce the Risk Impact?

Accept the Risk?

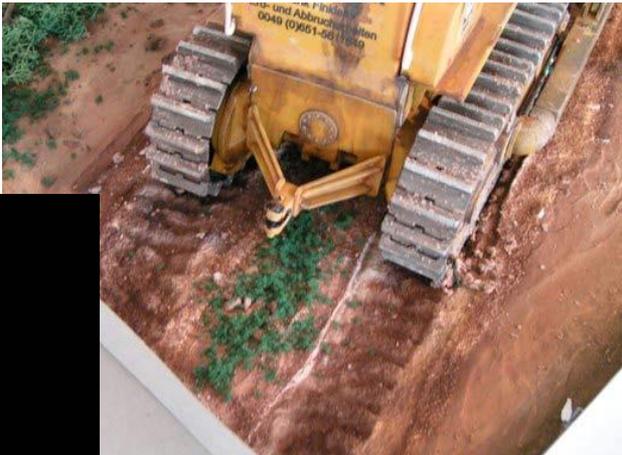


Process Risk

Process FMEA



Example: foundry process of track pads for excavators



Process FMEA template & inputs



Failure Modes and Effects Analysis Form (FMEA)

Process or Product Name: _____
 Process or Product Owner: _____ Project Leader: _____

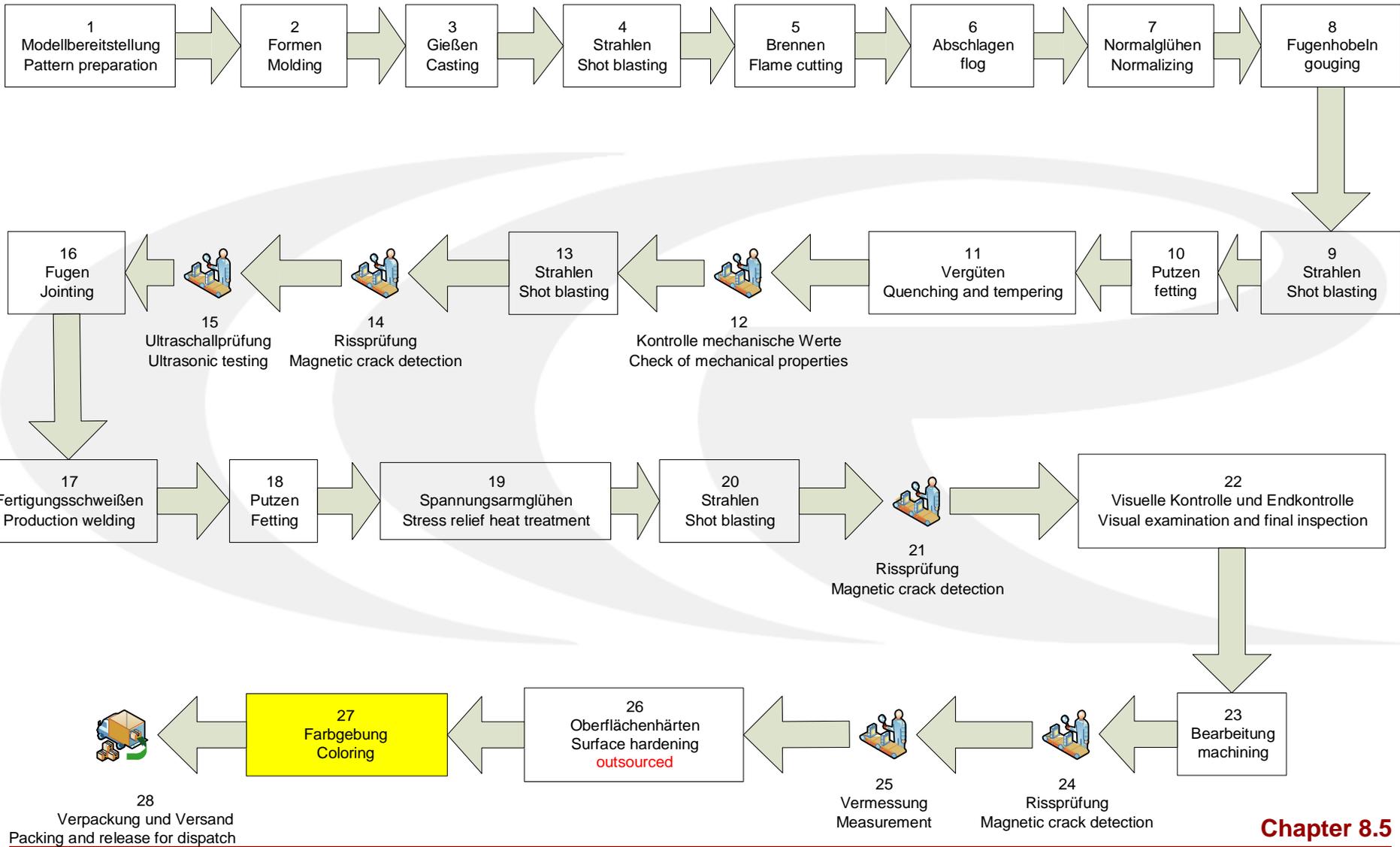
Facilitator: _____ Recorder: _____ Page ____ of ____
 FMEA Date (Orig): _____ Last Team Meeting Date: _____

Process Step/ Input/ Item	Function	Potential Failure Mode	Potential Failure Effects	S E V E R I T Y		P o t e n t i a l C a u s e s	O C C U R R E N C E	Current Controls Prevention	Current Controls Detection	D E T E C T I O N	R P N	Actions Recommended	Resp. & Target Date	Actions Taken	S E V E R I T Y		O C C U R R E N C E		D E T E C T I O N		R P N
What is the process step, Input or design item under investigation?	What is the Intended Function of the Step/ Input/ Item under investigation	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?			What causes the Key Input to go wrong?		What are the existing controls and procedures that prevent either the cause or the Failure Mode?	What are the existing controls and procedures (inspection and test) that detect either the cause or the Failure Mode?		0	What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?							0
											0										0
											0										0
											0										0
											0										0



Process flow chart

Manufacturing process of track pads - flow chart

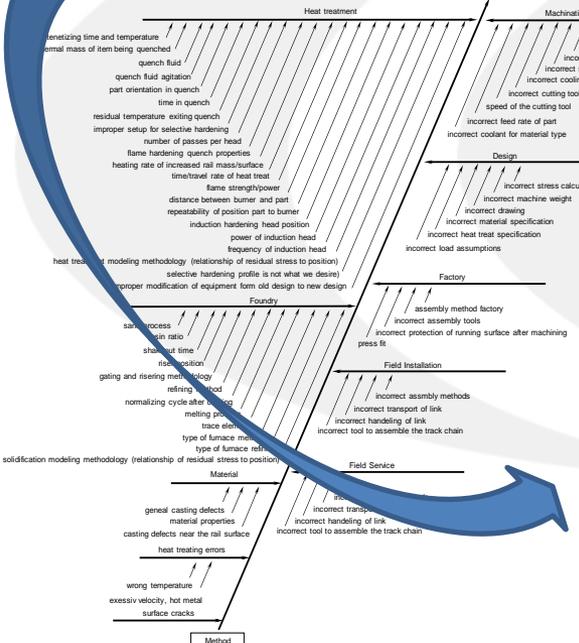
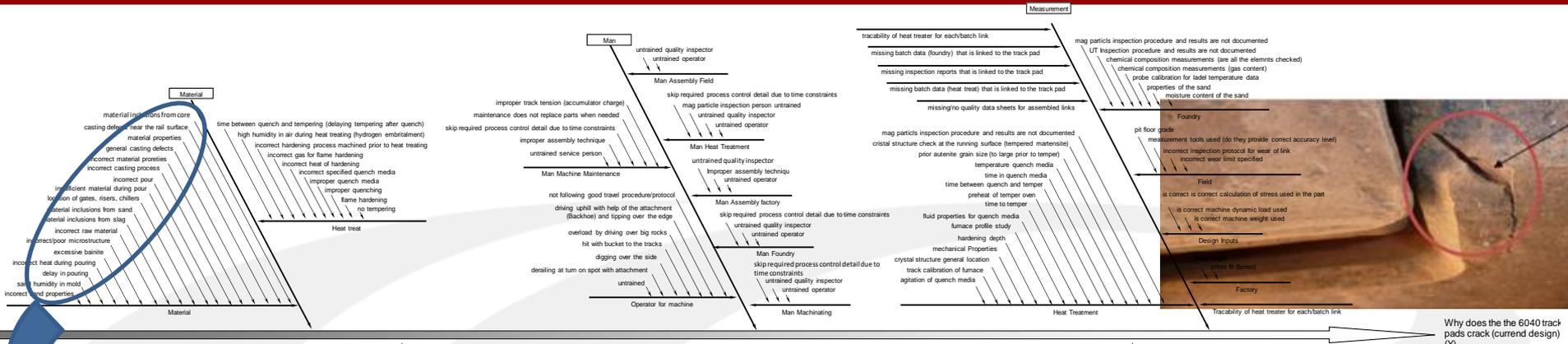




coloring (SIPOC) (Supplier, Input, Process, Output, Customer)

step	supplier	input	process	critical functions / parameters	output	customer
1	Surface hardening	traveller employee sample castings and samples	check identity / compare traveller with castings	eye function lighting accompanying documents component labeling training & qualifications suitability and condition of the slings environmental conditions	matching identification on castings and accompanying documents	
2		spray system cleaning material	system cleaning	cleanliness of spray system	clean spray system	
3		casting solvent	visual check and cleaning as necessary	cleanliness of casting	clean casting	
4		oven	predrying	temperature	dry casting	
5		color spray systems color mixer paint instruction color comb	1st primer	color material viscosity mixing ratio mixed technique layer thickness adhesiveness primer method Purity of color	primed part	
6		oven carousel	1. dry	time temperature	dry part	
7			more priming and dry	as in 1st primer		
8		dry film thickness gauge	inspection	dry film thickness	part with correct film thickness	
9		slings crane storage location	put on local storage	stacking sequence & technology state of storage	part painted / finished and ready for transport to next stage	
10		employee slings crane palette	prepare for transport	slings	prepared part	
11		traveller employee	entry in traveller	filling of template	dokumented information	
12		employee workstation time ticket	data entry in ERP system	data errors	confirmed part	packing and release for dispatch

Cause / effect diagram (Fishbone / Ishikawa)



MATERIAL (MATERIAL)		
1	incorrect material properties	
2	incorrect casting process	
3	incorrect pour	
4	insufficient material during pour	
5	location of gates, risers, chillers	
6	material inclusions from sand	
7	material inclusions from slag	
8	material inclusions from core	
9	incorrect raw material	
10	incorrect/poor microstructure	
11	excessive bainite	
12	incorrect heat during pouring	
13	delay in pouring	
14	sand humidity in mold	
15	incorrect sand properties	
16	casting defects near the rail surface	
17	material properties	
18	general casting defects	

probably no High influence
 probably significant influence
 probably very High influence

Risk evaluation scheme

		severity		
		10	5	1
occurrence	10	10 5 1	10 5 1	10 5 1
	5	10 5 1	10 5 1	10 5 1
	1	10 5 1	10 5 1	10 5 1

detection

action mandatory

action recommended

no action required

	severity	occurrence	detection
MEANING	<i>If damage or loss occurs, what is the effect on the internal and external customers or the next production step?</i>	<i>What is the probability that the cause occurs?</i>	<i>How is our confidence that we know the cause, or the cause of failure before it goes to the next step?</i>
10	irreparable part leads to scrap machinery failure leads to production downtime accident at work resulting in lost work time (sick leave) "I do not know..."	failure often occurs (min. 1x / month) "I do not know..."	almost impossible - no failure detection; can not be detected or is not checked.
5	component failure causes (unplanned) overtime equipment damage resulting in no loss of production injury leads to time loss (no sick leave)	failure occurs	low - inspection is not planned, it is checked indirectly or by sampling
1	no discernible effects	failure is very rare (max. 1x / year)	high - inspection or test reliably detects the error

Results of the process-FMEA (extract)



predrying	temperature	too low temperature	residual moisture is too high	5	burner defect	1			1										
1st primer	color material	wrong shade of color	there are parts that can not be blasted => intensive washing process	5	wrong requirements working error	1		production is controlled by QC later	5										
	viscosity	too high	only limited processability	1	wrong requirements working error	10		Sample for target-performance comparison; for new parts measuring of viscosity	1		no further actions								
	viscosity	too low	extra work due to runners	1	wrong mixing ratio	10		Sample for target-performance comparison; for new parts measuring of viscosity	1		no further actions								
	mixing ratio	wrong mixing ratio	affects the curing	5	data sheet missing working error calculation error	1			10		duty to provide training								
	mixed technique	color wrong mixed (time too short)	affects the quality of paint	5	lack of care time pressure	1			1										
	layer thickness	too less	minimum dry film thickness is not reached	5	paint too thin casting geometry	10			10		measurement of wet film thickness at defined measurement points								
	layer thickness	color runner	rework / repaint	1	paint too thick casting geometry	10	visual check		1										
	adhesiveness	no adhesiveness of color	color flakes	5	no clean underground incorrect mixture	1	visual check		10										
	primer method	wrong method	requirements (time, layer thicknesses, etc.) unachievable	5	no documented information	10			10		paint instruction								
	Purity of color	pollution	particle inclusions in the color layer	5	skinning through open paint container no order / cleanliness in the workplace	1			1										
	adhesiveness	shelf life of the opened color container exceeded	affects the quality of paint	5	shelf-life is not known	10			10		request shelf life data for opened container from supplier								
1st dry	time	too short	paint is not dry subsequent drying delay	5	temperature humidity	1			1										
	temperature	too low	paint is not dry subsequent drying delay	5	ambient temperature burner failure humidity	1			1										
more priming and dry	as in 1st primer																		
inspection	dry film thickness	too thin	minimum dry film thickness is not reached claim	5	paint flaws / handling	5			1		Sampling inspection of wet film thickness (to be put in paint instruction)								
	dry film thickness	color runner	rework / repaint	5	casting geometry technology-related	10			1										
put on local storage	stacking sequence & technology state of storage	castings are stacked	damage to the paint	1	no interlayer (no customer demand)	10		repainting	1										
		pollution	dirty surface	1	no top cover	10		blow off	1										
prepare for transport	traveller	missing accompanying documents	production stop	5	lack of care	1			1										
prepare for transport	filling of template	failure in data entry poor legibility	search effort	5	human error	1	annual training	supervisor / coordinator checks time ticket prior to data entry	10		improve ERP system regarding machine readable codes sample checks by shift supervisor								
entry in traveller	reading the time tickets	wrong data gathering on time ticket	no readiness of parts in system possible scrutiny needed	5	lack of care	10			1		omission by machine readable codes								
data entry in ERP system	entry	wrong data entry	no readiness of parts in system possible scrutiny needed	5	human error, lack of care	1			10		2nd check after data entry		shift supervisor	01.10.2014	5	1	1		
	entry	too late data entry	delayed process	5	wrong documented information	1			1										

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