IRIS ACADEMY

Guideline No.8

Risk- & Opportunity Management

April 2019

DRAFT

- is currently being checked for better English by a native speaker -

INTERNATIONAL COMPETENCE CENTRE RAIL

The Author

Andreas Heinzmann is one of the three initiators of the system houses Alstom, Bombardier and Siemens, 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 remained active as an IRIS Steering Committee and IRIS Advisory Board member. He took over, for example, together with Marcus Schmid (Voith), the final editing of the IRIS Revision 02 in 2009. In addition, in 2015 he cooperated in the 5-member core team together with Olivier Ringotte (Alstom), Sabrina Paeglow (Siemens), Emilio Sereni (Bombardier) and Angela de Heymer (UNIFE/IMC) on the draft of today's ISO/TS 22163:2017.

First with AEG-Westinghouse Berlin, and later with AEG in Hennigsdorf, he became involved in several 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 Adranz'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 as the 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 industry 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 master's in electrical engineering. Today he is one of the owners of International Competence Center Rail GmbH.

Hardly anyone else has had such a decisive influence on the content of the IRIS standard and can report on background information and interpretations in detail.

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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, however, members of 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 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 first and foremost the very 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 like a red 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, there is also a presentation on the same topic, which you will find in the appendix. The guideline contains several cross-references, which refer to the images contained therein. You can recognize such references 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 Neither ISO 9000 nor IRIS contain definitions of this term. Therefore, the term was derived by me.

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 labor, 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):

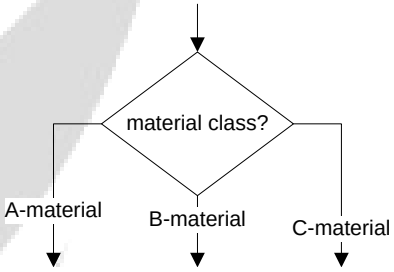
Method for process representation.

5 RISK-BASED THINKING

Risk-based thinking often happens unconsciously, without thinking much about it. 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. Always, if you read there "... *type and extent of controls* ...", then you 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, 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 not to turn completely freely, 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, which must 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 been exceeded.

For example, you start a project-FMEA already in the tendering process, because then you can 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 estimate the probabilities very roughly. 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 of risk prevention. Preventive actions are directed against 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, often there will be a remaining risk, 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 analyses must be regularly repeated and updated. Here, too, you decide yourself when this should happen. You can either plan this according to 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 occur surprisingly (out of the blue). The effects do not differ. This always results in consequential failure costs (QDC), which you should collect, analyze 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 utmost important that you measure QDC in its full scope according to its definition. Otherwise you would miss enormous benefits of this KPI.

6.6 Learning from failures (knowledge management)

Long ago my COO had told me, "if mistakes happen, this is human flop. But mistakes just mustn't repeat." That's what it's all about. You must learn lessons in order to be able to respond 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. Hence, 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 to completely execute the risk management process for the business planning, but the method is free to choose. 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 that risks can harm 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 among themselves prior to release. Manager shall 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:

- when significant new development (e.g. new platform product),
- when design with significant changes / modifications,
- when new or significantly modified production requirements,
- when problems with similar parts in the past,
- when new materials or parts,
- always in case of particular safety aspects (see IEC standards)!
- when 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 thoroughly trains 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. Hence, 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 would have achieved a degree 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 usually 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 preventive actions, as in this example:

- modernization of gas installations (costs EUR 15,000 according to the offer of a specialist company)
- modernization of electrical installations (costs 10.000 EUR according to the offer of a specialist company)
- smoking ban (0 EUR)

What would you do? The smoking ban will certainly be implemented immediately. It costs nothing, but reduces the probability of occurrence, even if only very slightly (e.g. by 5%). There would still be a remaining risk of 45% x 100.000 = 45,000 EUR. But would you spend 15,000 EUR and/or 10,000 EUR from your budget to reduce a possible damage of 45,000 EUR? If so, the probability of occurrence would be drastically reduced to an estimated 1% and the remaining risk would be 1,000 EUR only. For this, however, you must invest a lot of money from your budget in the modernization of the warehouse. In this case I would be reluctant to do so and would search for cheaper alternatives, for example:

- closure of the warehouse and relocation to a rented warehouse (annual rental payments 5,000 EUR) to save time (remaining risk is low).

I would not consider signing a fire insurance (risk transfer) as this would not eliminate the causes. Also, the installation of a sprinkler system would hardly help (limitation of damage only).

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 you have gained experience in this field, 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 in the red on the project balance sheet.

I hope that I have been able to explain this method in a reasonably plausible way. Surely you 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). Therein I planned 3 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 project FMEA 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 achieve 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 project FMEA 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 processes-FMEA make sense in the following cases:

- when significant new technologies in production,
- when production process with significant changes / modifications,
- when problems with similar production processes in the past,
- when production of new products or new parts assembly,
- when processes with particular safety aspects,
- when special processes (gluing, crimping, soldering, plating, etc.),

- when automatic or semi-automatic processes with high complexity,
- when outsourced processes with high impact on product quality or safety,
- when manufacturing processes-FMEA is 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 existent special process. Ideally, this would be presented in the form of a process FMEA 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 process FMEA.

The development of a SIPOC seems to me to be indispensable. In this example, this table contains all the essential risk fields of the coloring 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. If all optional requirements of the IRIS Assessment Sheet were to be included, the number of pages would quickly double. If you want to learn more about this topic, you should attend our course IRIS Project Management (Link).

- - *End of the guideline* -

FEEDBACK

In case you do not agree with the content, please write me 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 to both for this!

In addition, I would also like to thank Simon Kenyon, who once again succeeded in transforming my English into a readable, understandable version.

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)

INTERNATIONAL COMPETENCE CENTRE RAIL GmbH

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.

Implementation of risk based thinking

- 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		Manufacturing process with adjustments Manufacturing processes with medium failure	5	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	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?

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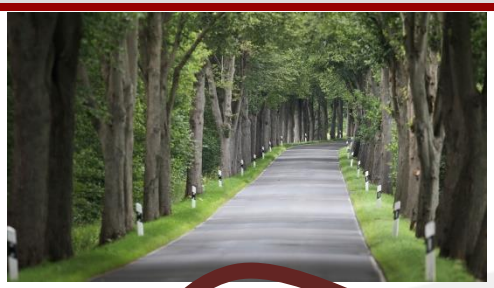
Planning

6.1 Actions to address risks and opportunities

Definitions



country road

t +1 containment action
= *immediate action to correct*

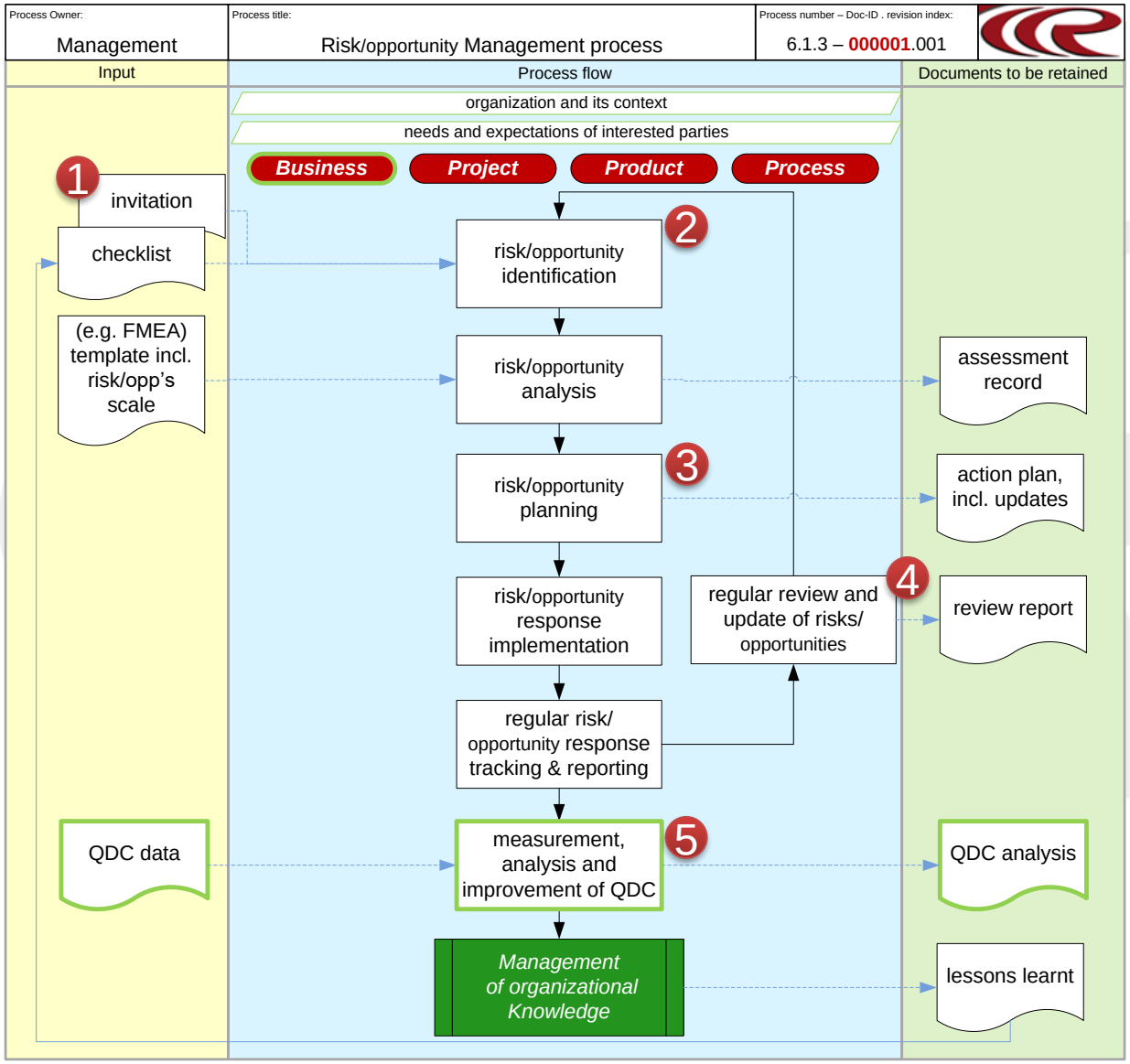
t +2 corrective action
= *action to eliminate the root cause in order it doesn‘t happen again*

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*

Chapter 6.1.3

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*

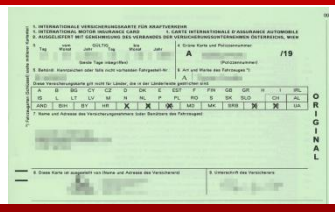
5 evaluate the effectiveness of risk management *based on QDCs*

Chapter 6.1.3

Planning of risk responses

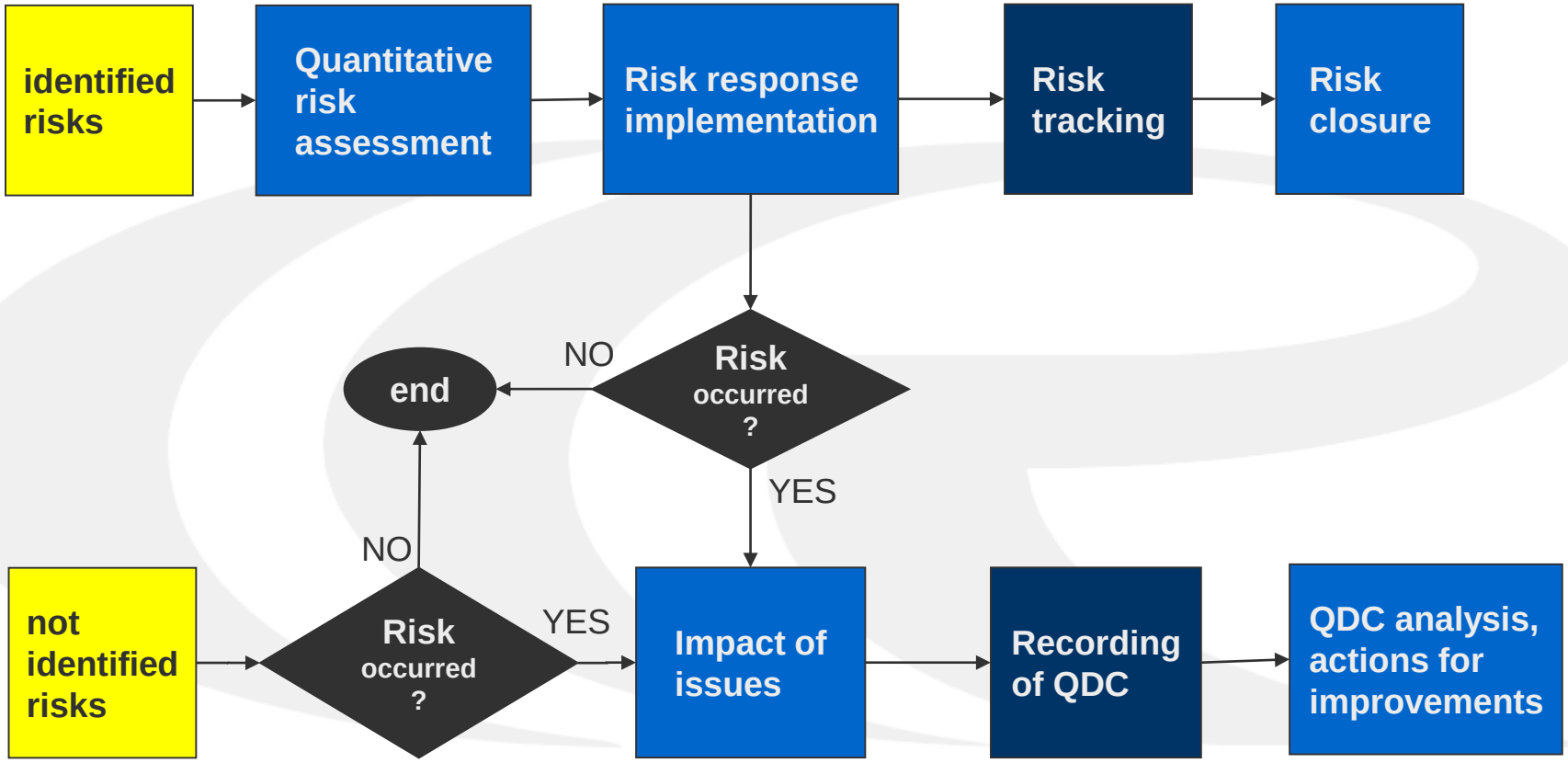
	risk avoidance	risk prevention	risk mitigation	risk transfer	acceptance of risk
	TOTAL RISK	action directed against the probability of occurrence or detection	actions to minimize the potential impact	transfer of risks, e.g. by insurance contracts	**REMAINING RISK**
	identified risks				
target:	exclude 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
	PREVENTIVE		**REACTIVE**		



Chapter 6.1.3

Risk management - measurements of effectiveness

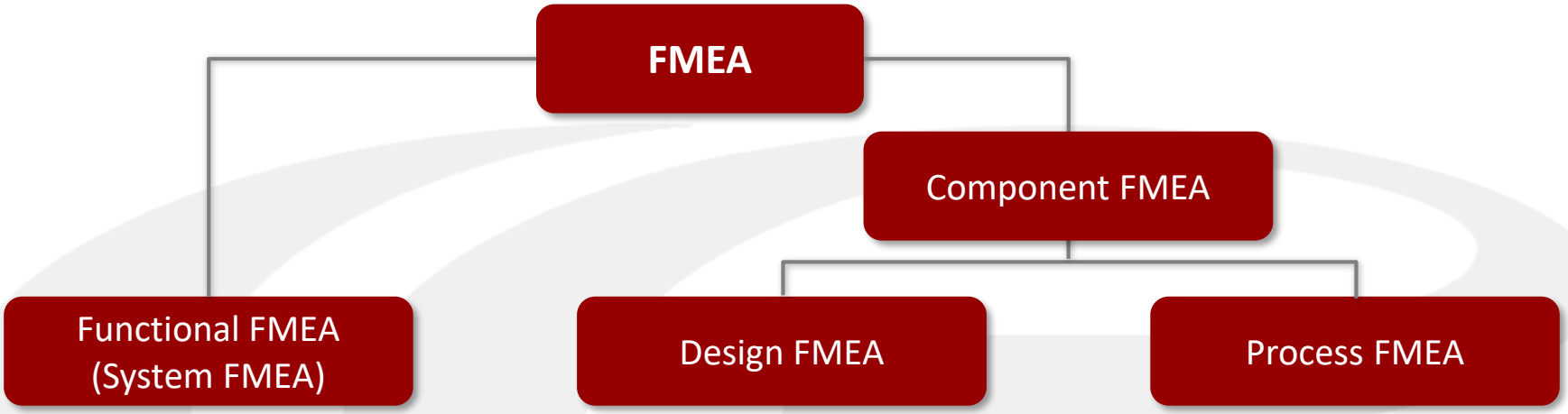


AH: "I'm convinced that Quality Management is profoundly logical. It's basically all about getting the risks under control."

Chapter 6.1.3

Failure Modes and Effects Analysis

Versions of the FMEA



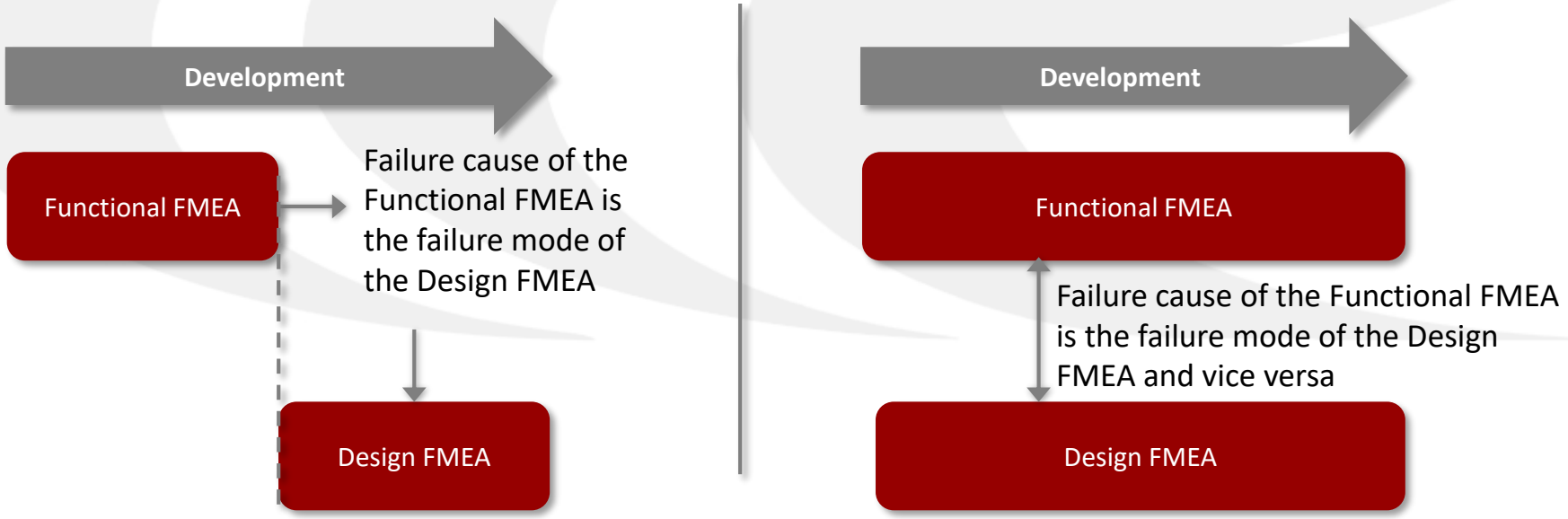
- Identification of weak points in the system layout and configuration
- Analysis of the effect of functional failures
- Derivation of improvement measures within the system architecture
- Aim: Improve reliability

- Identification of weak points in the system (component) design
- Analysis of the potential failure modes of system components
- Strengthening of component design (e.g. environmental resistance)
- Aim: Improve reliability (quality)

- Identification of weak points in the manufacturing process (also operation and maintenance)
- Process failures (human errors, machines, methods, etc.) are analyse with regard to their impact of the system and/or components

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

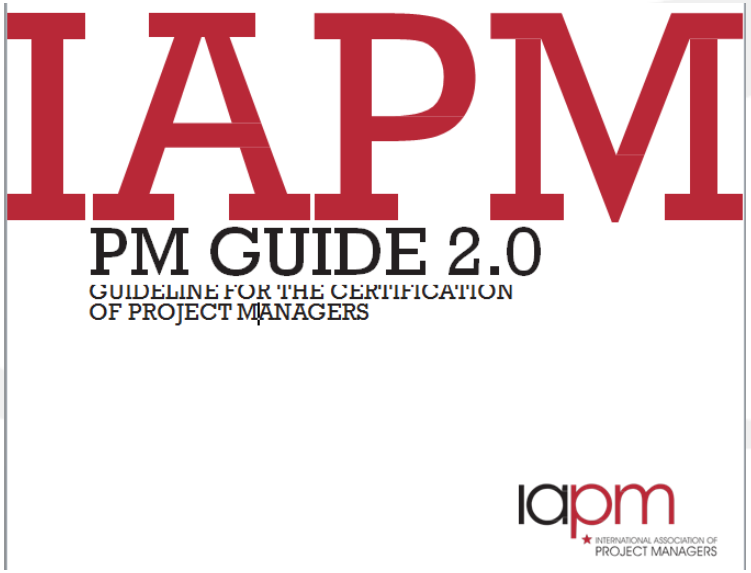
6.1. Business Risk and
6.1.4 Contingency Planning

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

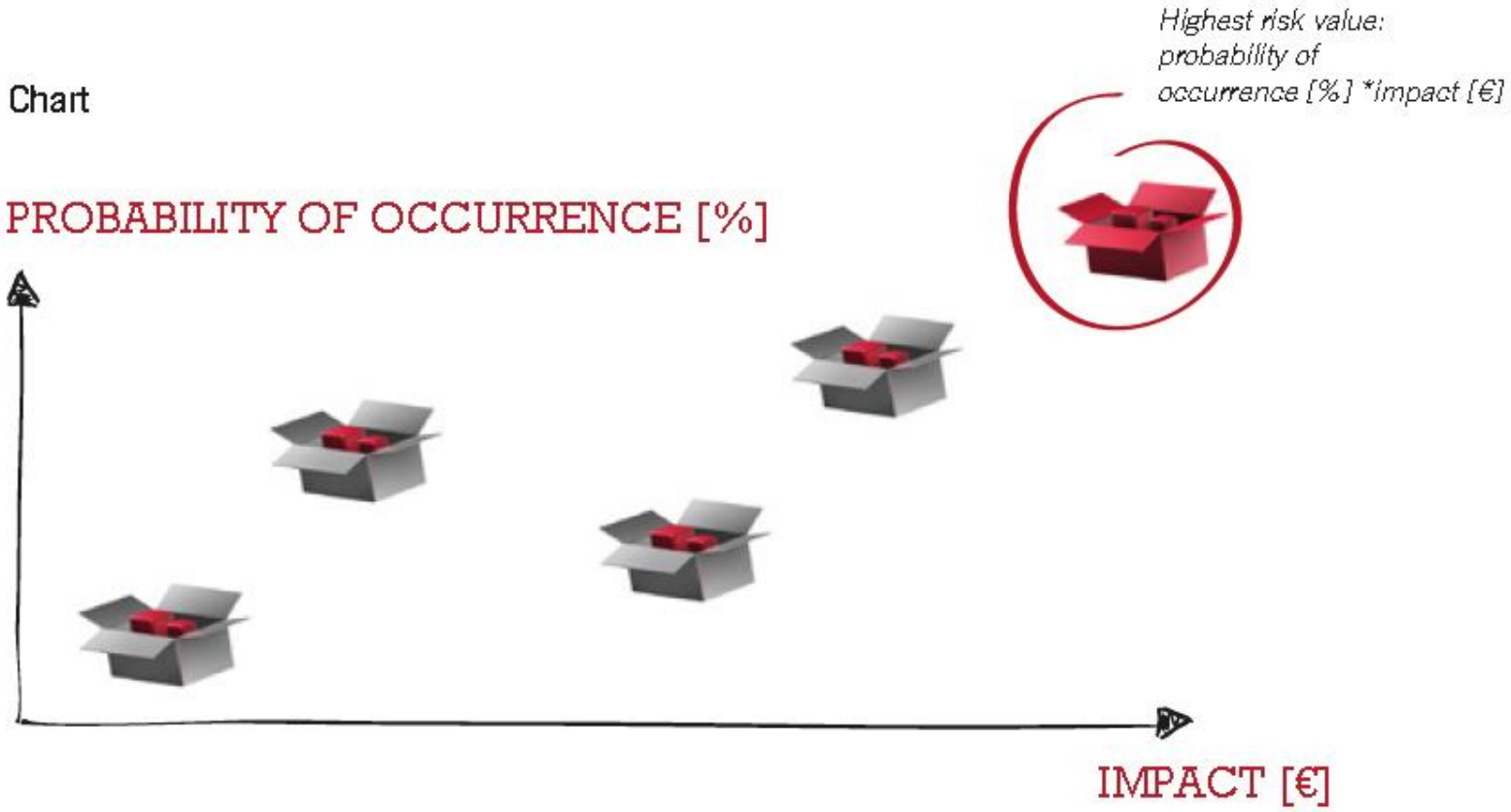
recommended lecture:



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

Monetary weighted RISK ANALYSIS

monetary evaluation of risks:



Risk - causes

fields of risks:

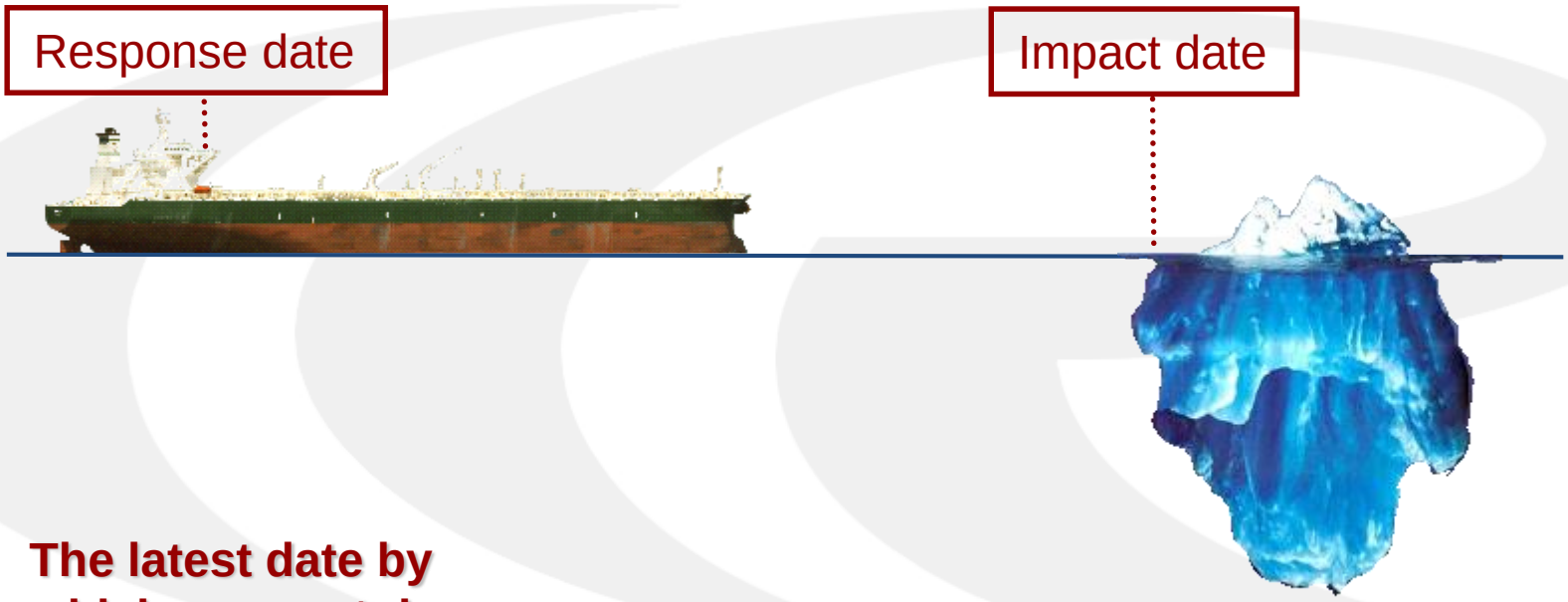
One risk may have an impact / influence on other risks.

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?

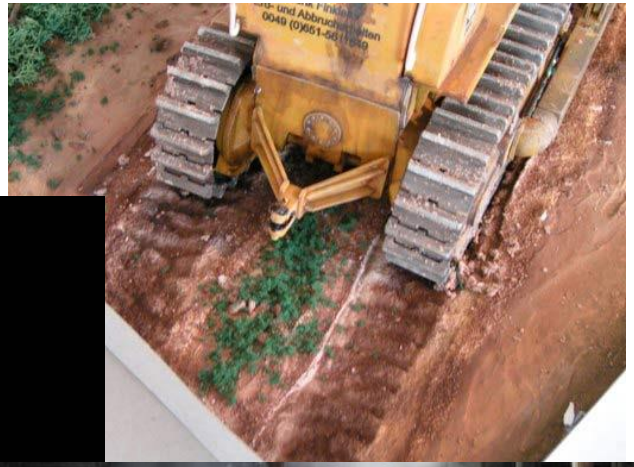
Reduce the Risk Impact?

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	SEVERITY	Class.	Potential Causes	OCCURRENCE	Current Controls Prevention	Current Controls Detection	DETECTION	RPN	Actions Recommended	Resp. & Target Date	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
What is the process step, Input or design item under investiga-tion?	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?			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
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Process flow chart

SIPOC

Fishbone

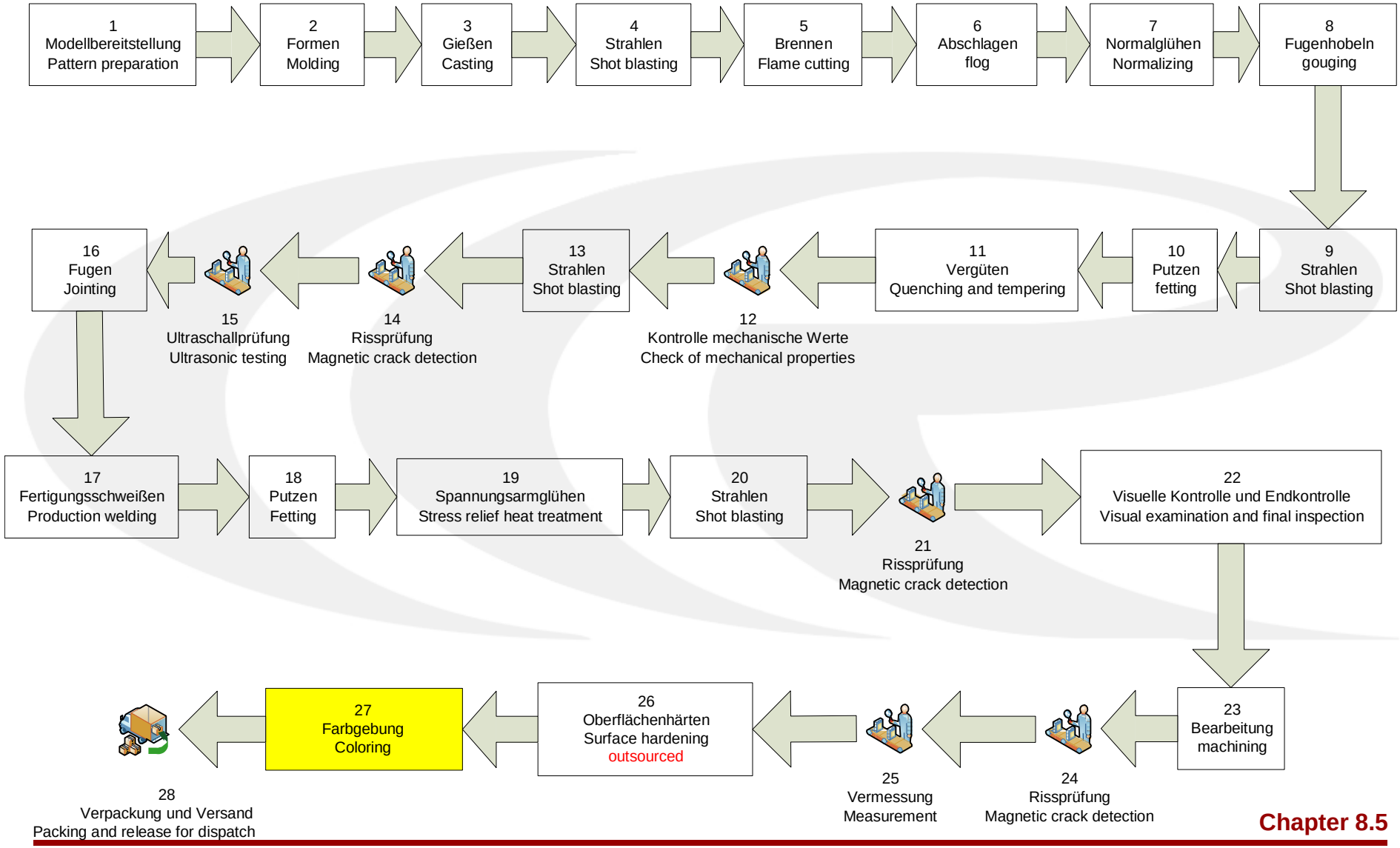
Inspection and test plan

Risk evaluation and action plan

Re-evaluation

Chapter 8.5

Manufacturing process of track pads - flow chart

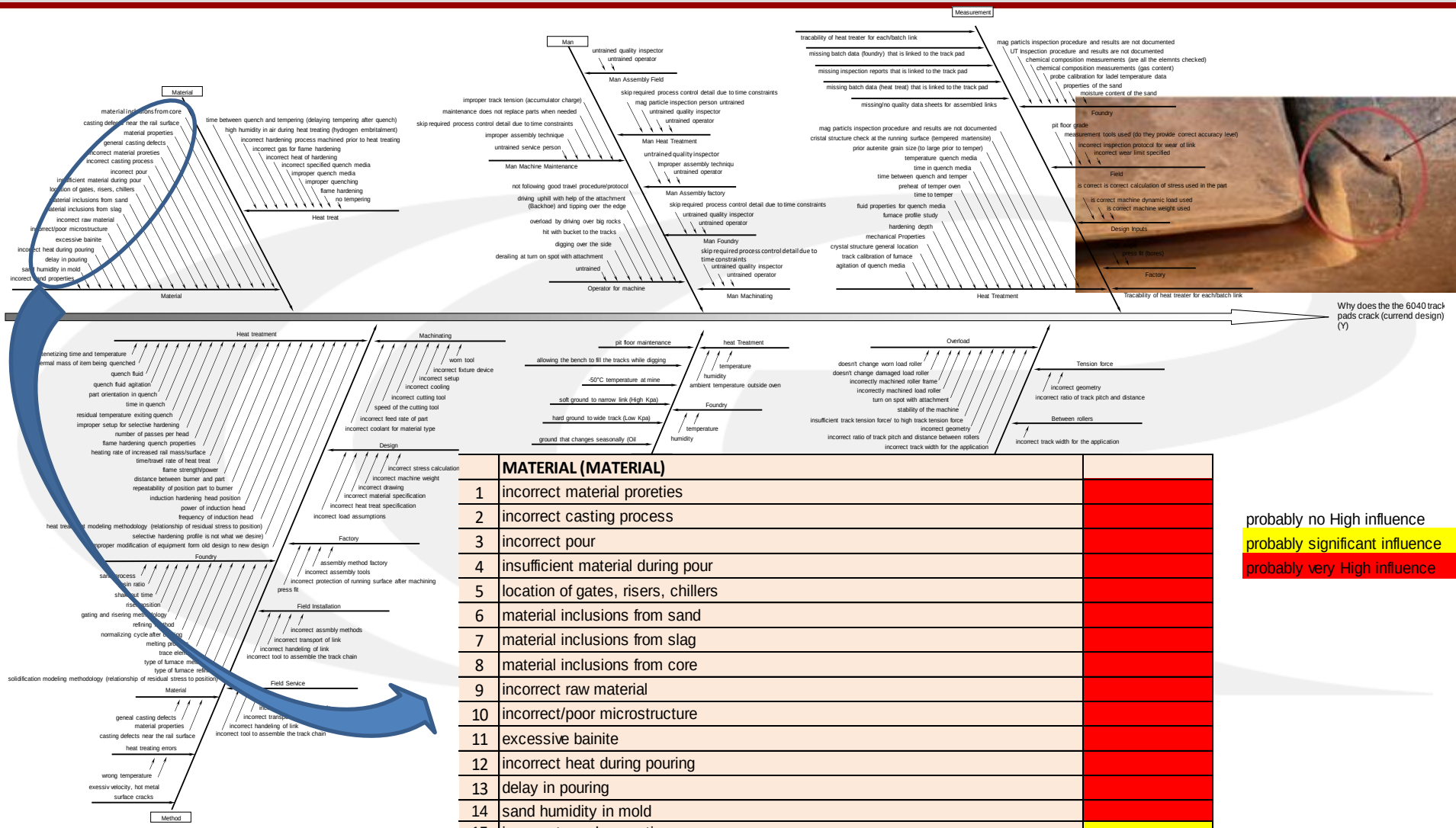


SIPOC

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 proreties	
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

Chapter 8.5

Risk evaluation scheme

	severity	occurrence	detection
MEANING	*If damage or loss occurs, what is the effect on the internal and external customers or the next production step?*	*What is the probability that the cause occurs?*	*How is our confidence that we know the cause, or the cause of failure before it goes to the next step?*
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 thinn 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 thinn	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									
	state of storage	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									

Chapter 8.5

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