INTERNATIONAL COMPETENCE CENTRE RAIL GmbH

Welcome to the „HIGH SCHOOL“ for IRIS Manager

Preview of coming ISO/TS 22163 requirements

(NOTE: this information are not finally released yet;
changes may occur after publishing the norm in May 2017)

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IRIS ACADEMY

Your tutor

First and last name

Andreas Heinzmann

Citizenship

German

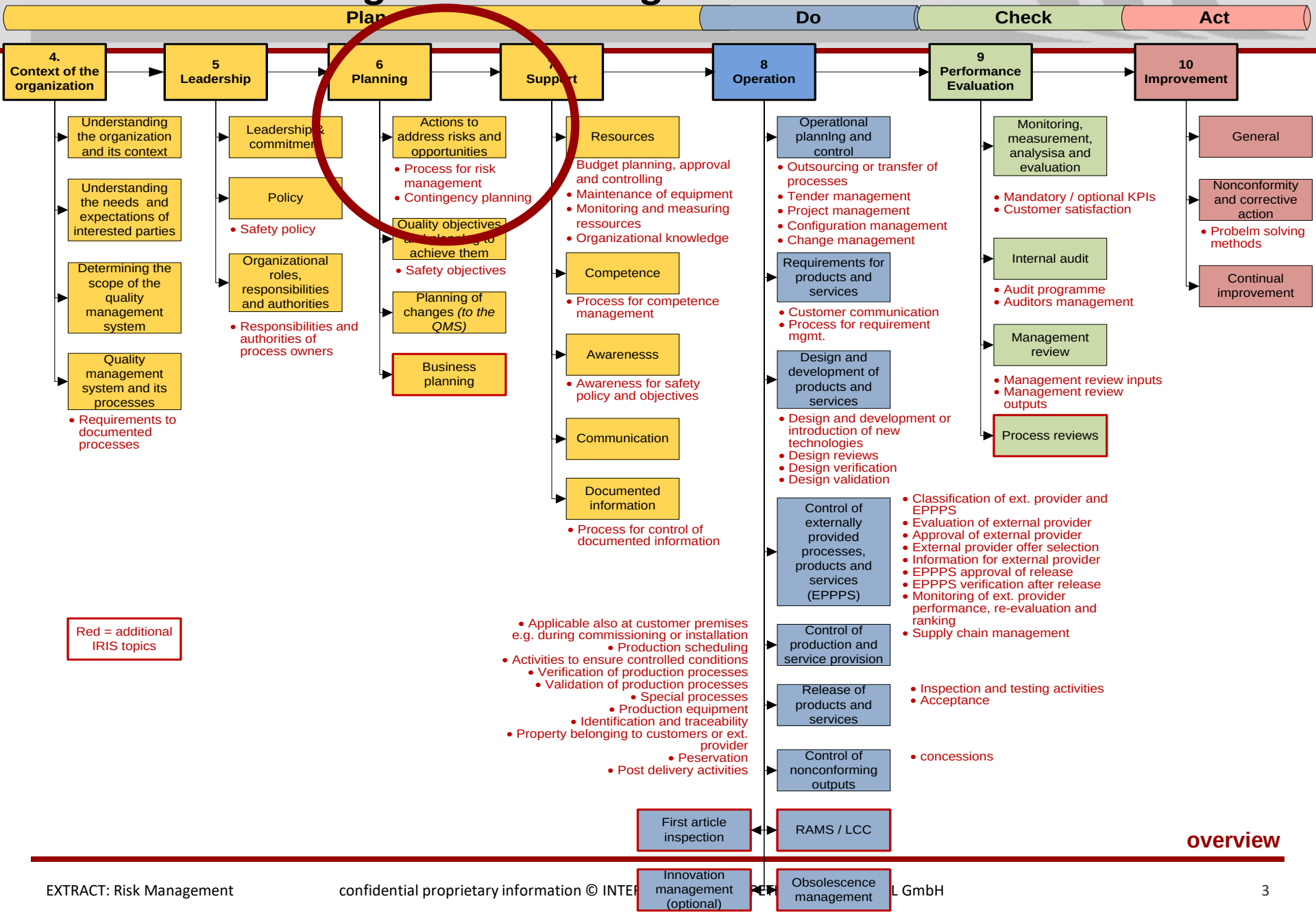
Special strength / knowledge in the area of quality, certification, IRIS etc.

- one of three initiators of the IRIS standard and 1st President of the IRIS Group,
- responsible for the content and the successful launch of the IRIS certification (2006)
- from the beginning until today consistently involved in all IRIS revisions;
- one of the 5 member core team, which were commissioned to draft the new IRIS / ISO standard (2015/2016),
- more than 800 IRIS internal auditors trained and 38 companies (~52'000 employees) were successfully prepared for IRIS certification,
- IRIS witness auditor for supervision of IRIS approved certification bodies.

Professional career

- Masters degree (Dipl.-Ing.) in Electrical Engineering.
- 1990 AEG-Westinghouse Berlin > AEG in Hennigsdorf, (Shanghai Metro, BR12X, VT 611/612).
- 1998 head of QHSE in Adranz's "Light Rail Vehicles" Business Unit in Nuremberg.
- 2000 Bombardier (DWA) as General Manager for Quality & Customer Service.
- 2002 Senior Director Quality at Bombardier Transportation's headquarters
- > 35 years professional experience > network of suppliers, operators, approval authorities and registrars, also in the automotive, aerospace and food industries.
- I have been working in a second capacity as lead auditor, trainer and consultant as far back as 1995
- 2009 foundation of iCC-Rail GmbH, the global market leader in IRIS training, coaching and mentoring.

IRIS elements integrated in ISO high level structure



0.3.3 Risk based thinking

Implementation of risk based thinking (1)

- 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, see also page 68, processes for EPPPS)

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

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

Risk based thinking

Implementation of risk based thinking (2)

- Question:

Is it really necessary to manage all projects with the same care?

Implementation of risk based thinking
(best practices part 2)

Project classification scheme (see also process for project initiation & planning, page 51

	Complexity		Effort		Strategy		Degree of Novelty	
	Organizational Complexity	Technical Risk	Invest	Design hours	Customer	Product-Roadmap	Characteristics of Product	Production processes
Orders with PM principles	only one site involved **0**	low **0**	< 100.000 € **0**	< 500 hours **0**	without customer requirements	low strategic importance **0**	Variation within a family or modification **0**	known processes, technologies, types of tools **0**
Regular order handling process	development and / or production at several sites involved **1**	medium or high **2**	> 100.000 € **1**	> 500 hours **1**	Customer requires Project Management	medium or high strategic importance **1**	new Product or new Product family **2**	extented technological requirements and / or new manufacturing technology **1**
					mandatory requirement			

NOTE: project management process depends on the business model of an organization. In most of the rail sector companies it is from tender phase until the end of warranty period. However in other cases it may be limited to design and development only (e.g. for the development of a new product family or platform)

Project management principles must be applied when,

- the mandatory requirement is met, or
- the sum of scoring is more than 4

Remark: Due to business decisions the upgrade of an order to a project is possible at any time, even if the criteria are not met. But not visa versa!

Risk based thinking

Further applications of 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?

…..

Risk based thinking

Risk management tools

When do we conduct a FMEA?

Product design FMEA

- 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
- high complexity regarding functional or integration requirements
- FMEA is required by customer or standards

monetary weighted Project FMEA

- starting in tender phase (baseline FMEA)
- regular updates (e.g. monthly, quarterly or once per project phase)
- till end of project life

Production process FMEA

- 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
- FMEA is required by customer or standards

Business risk assessment and contingency plan

- regular update at least once a year
- @ defined month in acc. with strat. business cycle

Risk based thinking

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

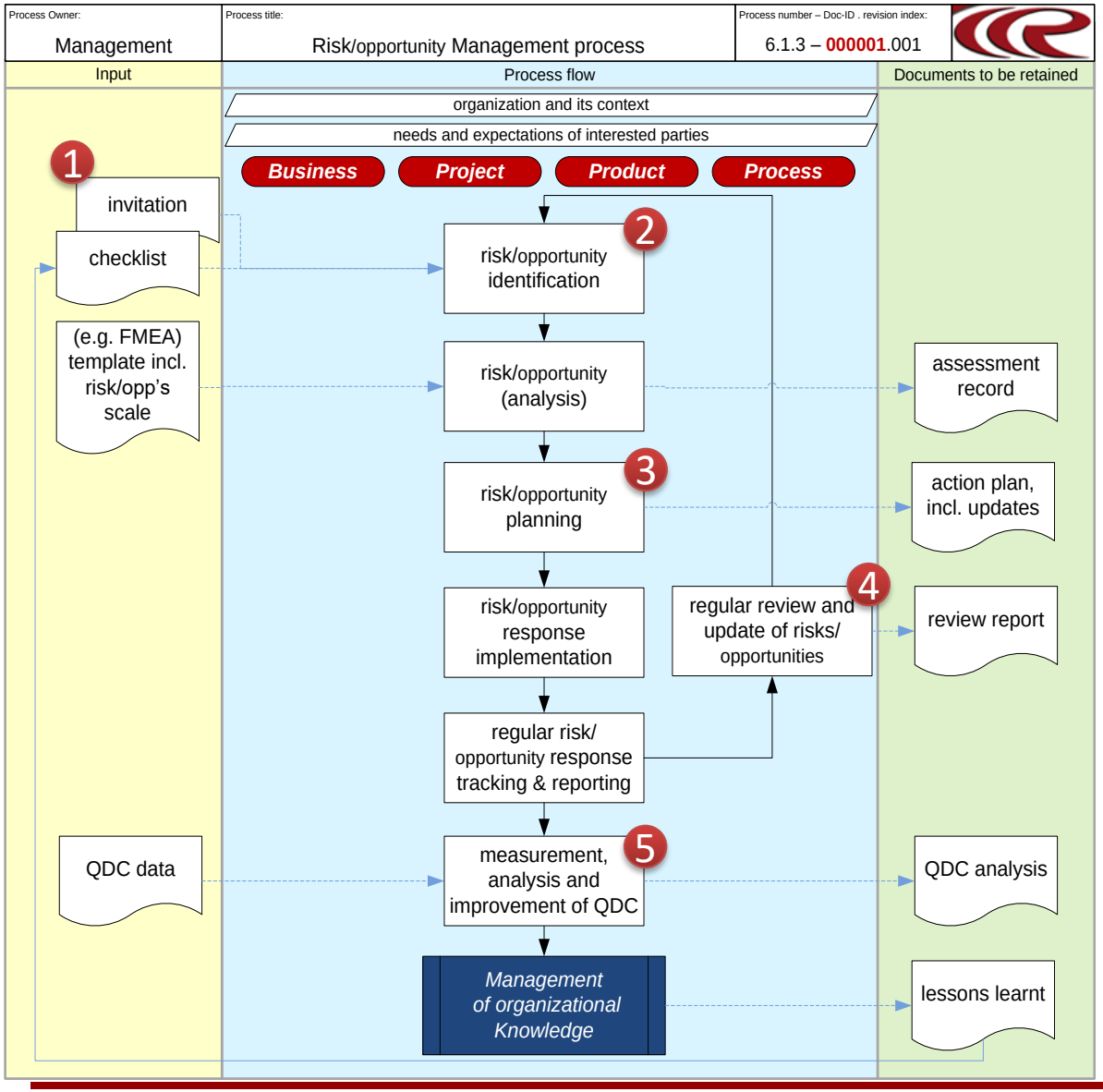
= *action to eliminate the root cause of a potential issue in order it doesn‘t happen*

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*

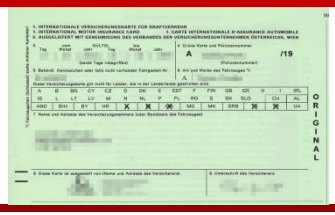
5 evaluate the effectiveness of risk management *based on QDCs*

Chapter 6.1.3

Planning of risk responses

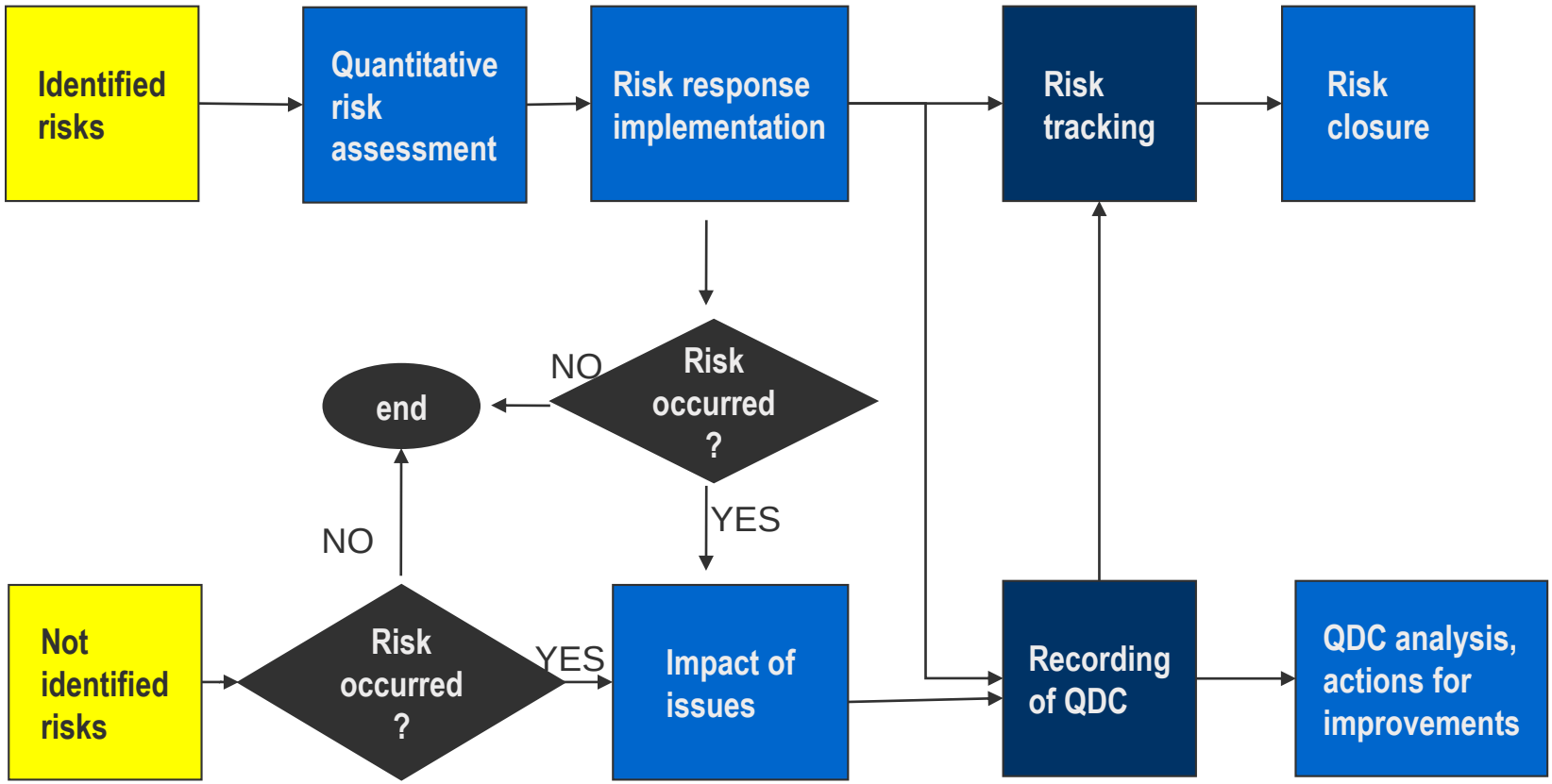
	risk avoidance	risk prevention	risk mitigation	accepted risks: risk transfer	accepted risks: acceptance of risk
	TOTAL RISK	action directed against the probability of occurrence or detection	actions to minmize the potential impact	transfer of risks, e.g. by insurance contracts	**REMAINING RISK**
	identified risks				
target:	exclude risk	prevention of the causes of occurrence or improve the possibility for detection	reduction or limitation of the demage	minimizing the consequences of the demage	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."

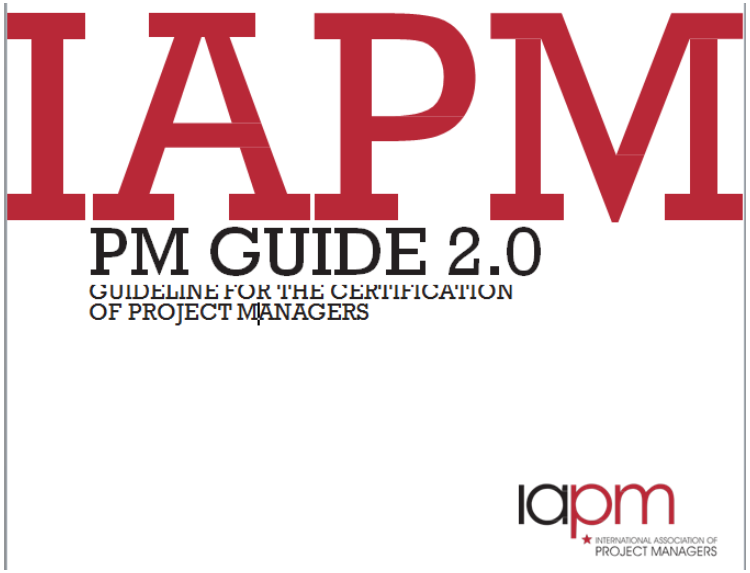
Chapter 6.1.3

Business Risk and Contingency Planning

This topic is currently omitted in this sample

Project Risk

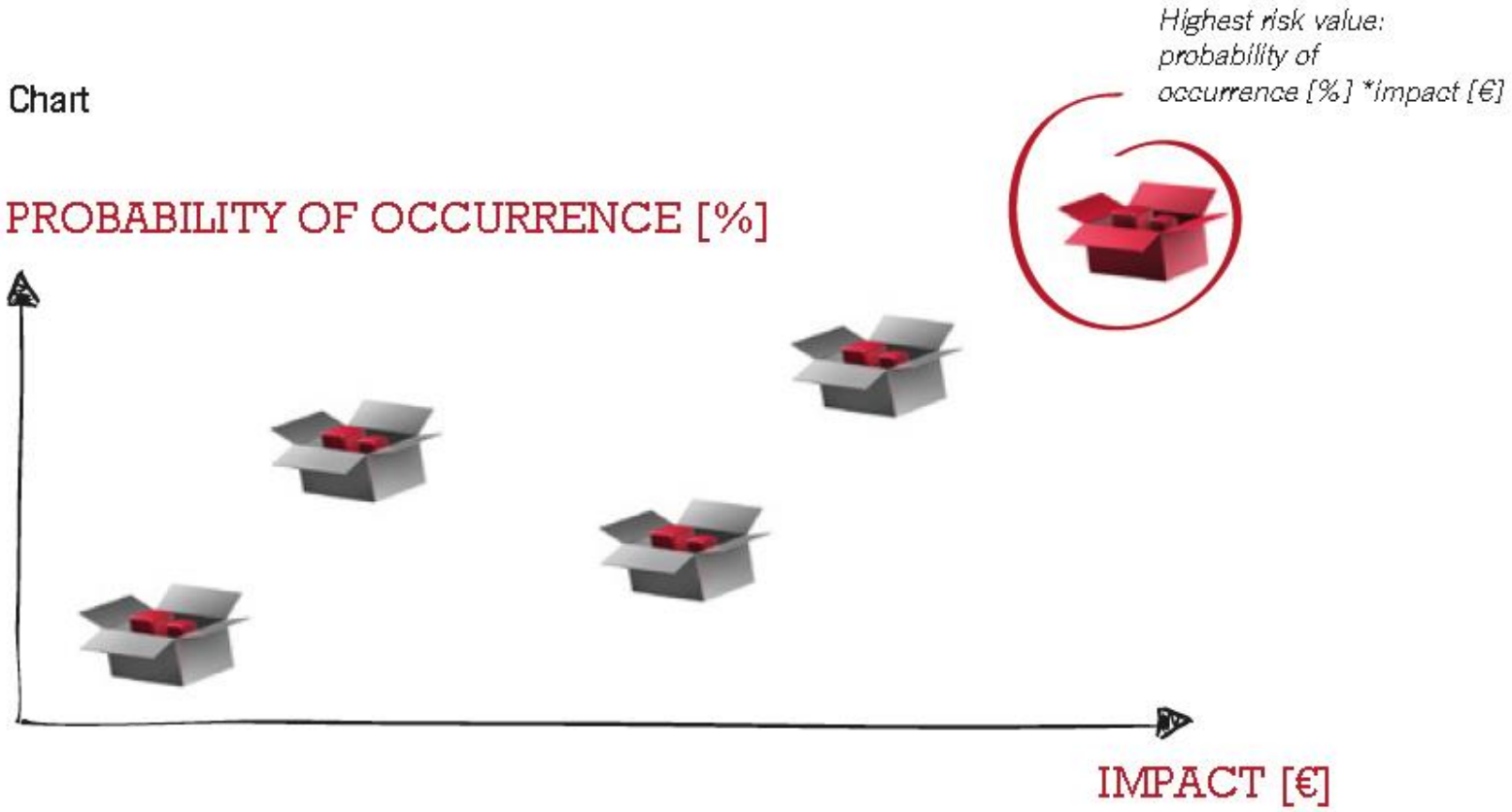
recommended lecture:



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

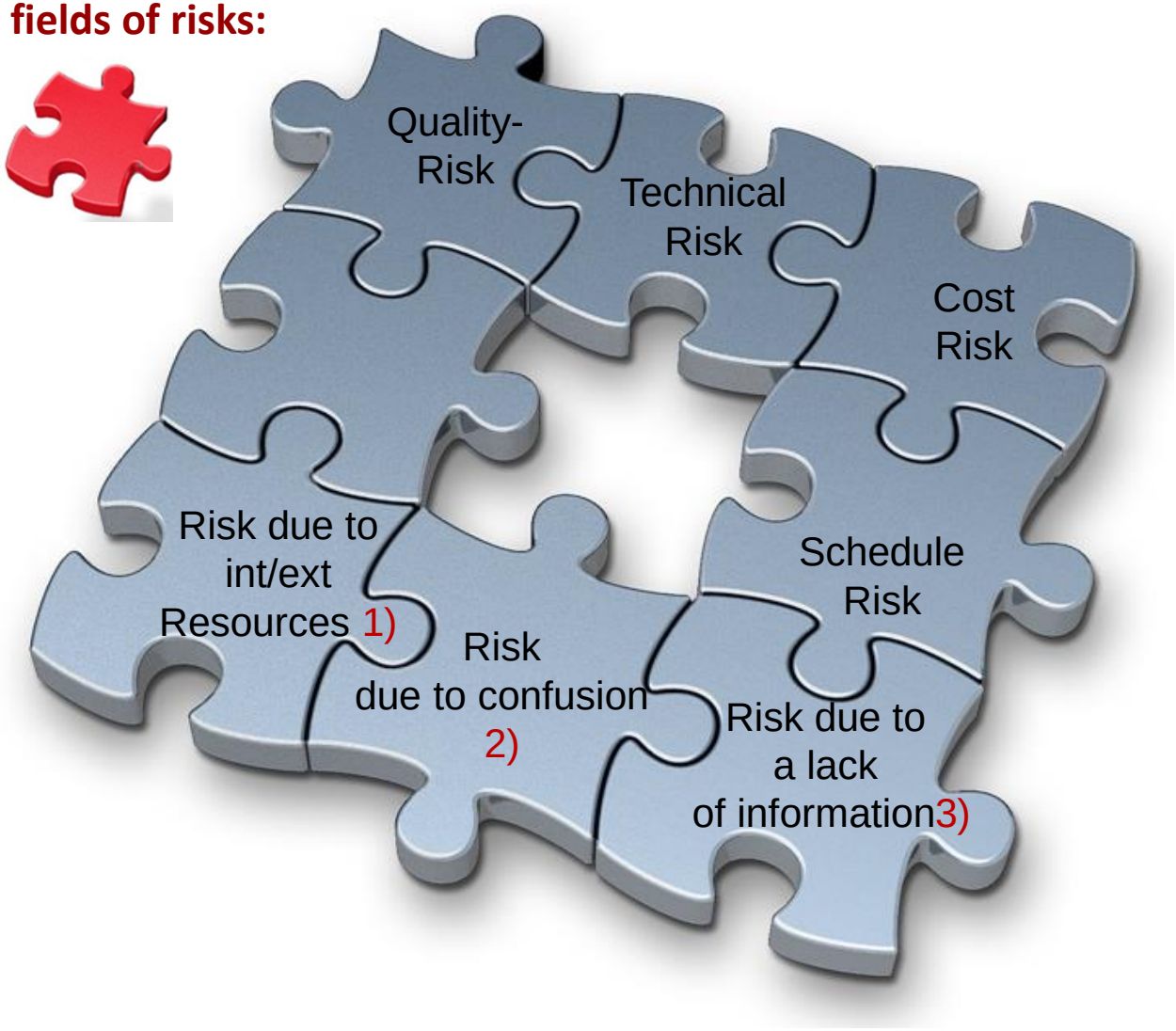
Monetary weighted RISK ANALYSIS

monetary evaluation of risks:



Risk - causes

fields of risks:



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.

Project Risks

Example: Define and Mitigate

example: define and mitigate

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

Mitigate practically and cost effectively:

replace gas & electrical works and ban smoking in warehouse!

Does the action target:

Transfer the Risk?

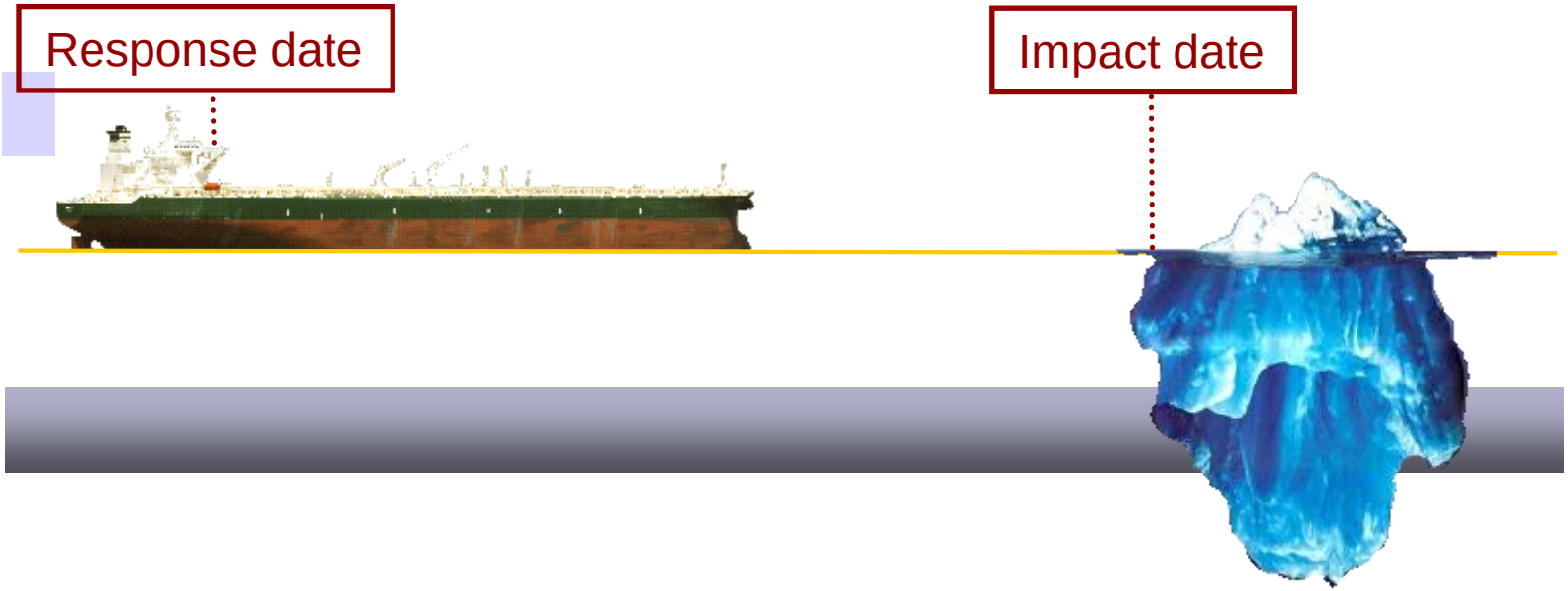
Target the Risk Cause?

Reduce the Risk Impact?

Accept the Risk?

Response date

Consider the response date!



The latest date by which we must do something.

Exercise 3: case study - Project FMEA

- Please split into groups.

- You now have time to complete a project-based risk assessment (FMEA methodology) in accordance with a case study. Please use your laptop and this

Excel Tool

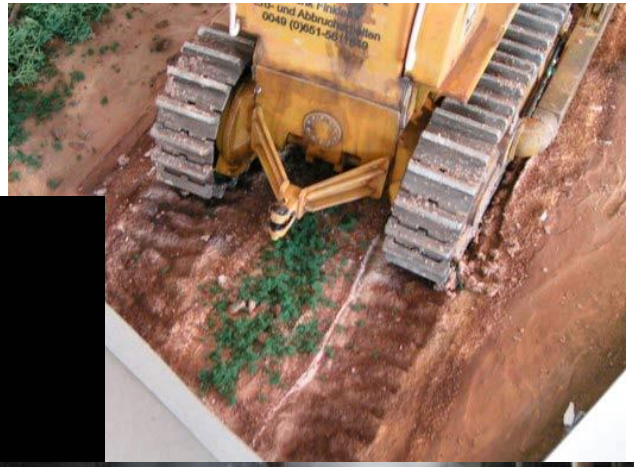
- Your goal is to support the decision-making process of your company prior to the first gate, i.e. before the offer will be launched.

What do you suggest? Offering or not?
I'm looking forward to your answers!

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
											0							0
											0							0
											0							0

Process flow chart

SIPOC

Fishbone

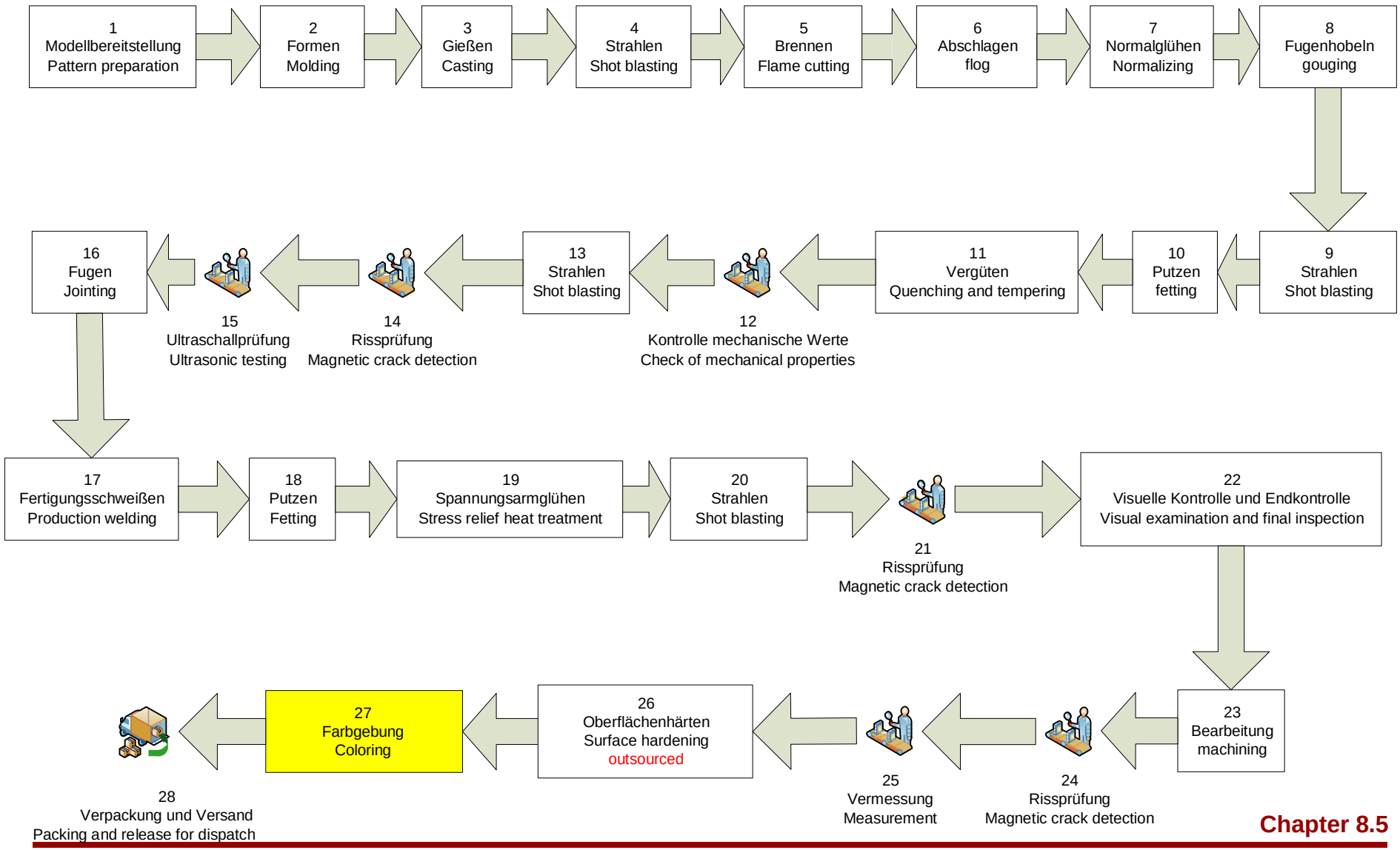
Inspection and test plan

Risk evaluation and action plan

Re-evaluation

Chapter 8.5

Manufacturing process of track pads - flow chart



Chapter 8.5

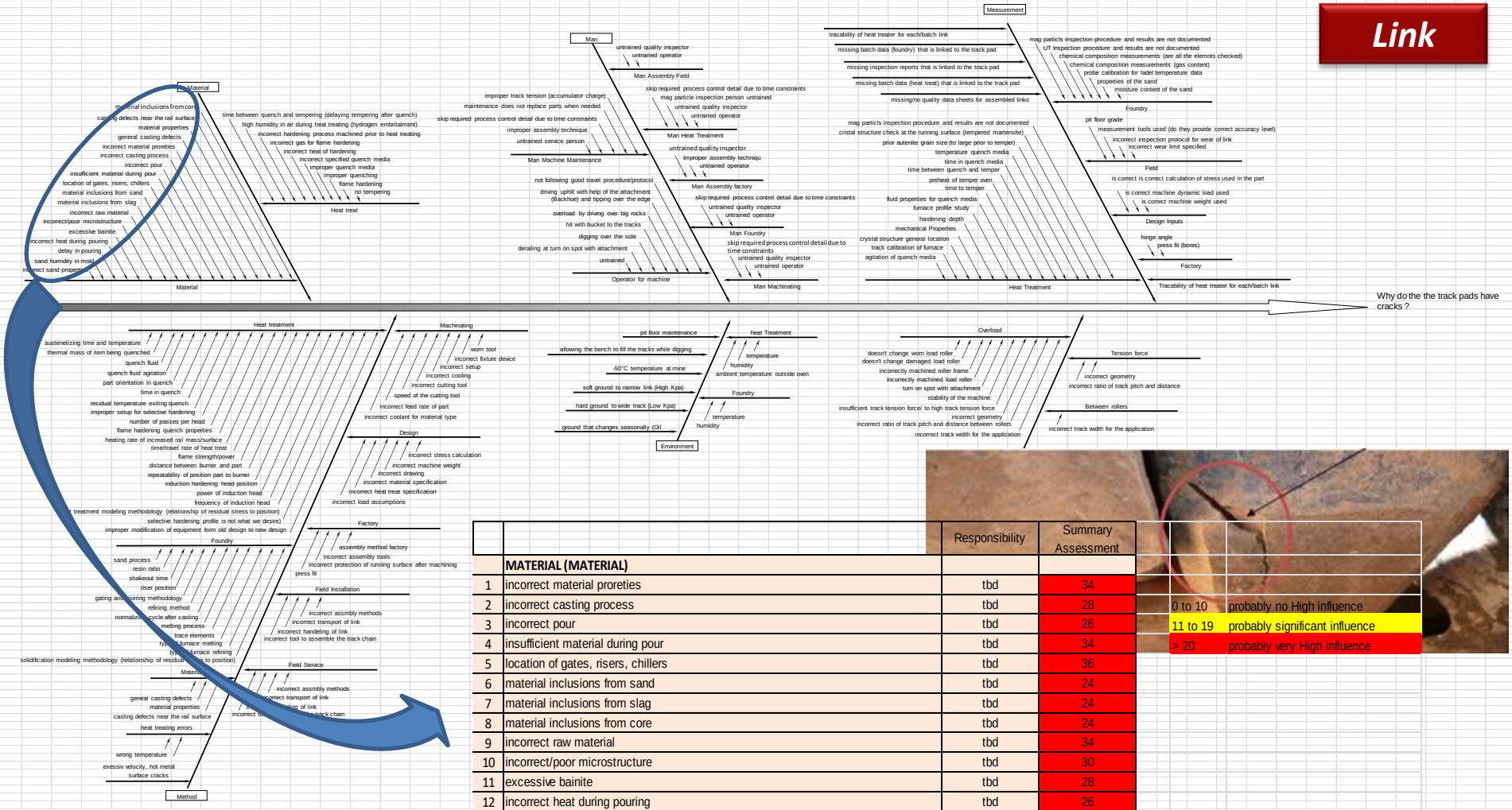
SIPOC

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)

Link

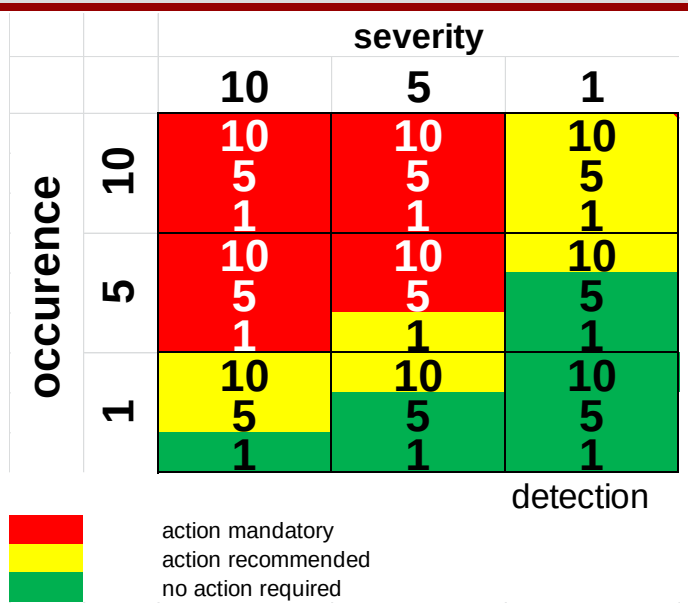


		Responsibility	Summary Assessment
	MATERIAL (MATERIAL)		
1	incorrect material proreties	tbd	34
2	incorrect casting process	tbd	28
3	incorrect pour	tbd	26
4	insufficient material during pour	tbd	34
5	location of gates, risers, chillers	tbd	36
6	material inclusions from sand	tbd	24
7	material inclusions from slag	tbd	24
8	material inclusions from core	tbd	24
9	incorrect raw material	tbd	34
10	incorrect/poor microstructure	tbd	30
11	excessive bainite	tbd	28
12	incorrect heat during pouring	tbd	26
13	delay in pouring	tbd	32
14	sand humidity in mold	tbd	20
15	incorrect sand properties	tbd	10
16	casting defects near the rail surface	tbd	32
17	material properties	tbd	36
18	general casting defects	tbd	30

0 to 10	probably no High influence
11 to 19	probably significant influence
> 20	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

Process-FMEA (1/2)

Process step	critical functions / parameters	failure	impact	severity	cause	occurence	actual preventive action	actual corrective action	detection	risk class	prevetive / mitigation action	budget	responsible	target date	severity	occurence	detection	risk class
identity check	eye function	wrong gathering of casting data from labeling	no traceability	5	poor eye function, no glasses	1	eye test every 2nd year		1									
	lighting	wrong gathering of casting data from labeling	no traceability	5	poor lighting	1	cleaning schedule		1									
	lighting	poor illumination (mind. 300lx)	wrong gathering of casting data	5	poor lighting	1	regular check by maintenance		1									
	component labeling	wrong gathering of casting data from labeling	no traceability	10	poor component labeling, mirrored reading	10	enlarge the font field	investigation by shift supervisor	10		a unique alignment of the title block, e.g. as underscore		Hr. Miller, N.	01.10.2014	5	1	10	
	accompanying documents	missing accompanying documents	non-acceptance	5	loss during transport no duty to bring docs to the next station	1		Information of the shift supervisor worker gets papers	1									
	accompanying documents	wrong accompanying documents	non-acceptance	5	lack of care	5	shift supervisor is responsible for care		1		training concept of stacking sequence & technology (countersign of transported castings on traveler)		head of department heat treatment	01.11.2014	5	1	1	
	training & qualifications	worker not trained	no traceability rework / repair	5	poor quality / capability of tutor / content of the training sickness / holidays	1	regular training 1 x /year traveler is also mentioned in other training		1									
	suitability and condition of the slings	casting fall down	accident at work	10	demaged sling	1	external review (annually); daily internal review by workers		1									
	environmental conditions	dirty work station	dirt particles in the paint; inclusions	5	missing cleannes	1			1									
	environmental conditions	too high humidity	blistering (small craters; porosity) poor binding ability of color	5	open hall system	1	predrying measurement of humidity		1									
	environmental conditions	too low temperature	too long drying time; Viscosity of the color is too high	5	open hall system	1	measuring the temperature Heaters in winter		1									
	training & qualifications	missing qualification pint instructuion not known/available	paint not to instruction	5	qualification deficiency lack of training	10	product-related training		10		training skill matrix							
system cleaning	cleanliness of spray system	paint residues in the intake and coloring system	inoperability	5	lack of care	10			1		Functional test before each shift and after each break							
visual check and cleaning as necessary	cleanliness of casting	contamination (dust, rust, test equipment residues)	Particle inclusions in the color layer	5	lack of order and cleanliness in production	5		blow with compressed air	1		improve stacking sequence & technology to avoid contact points and residual moisture							

Process-FMEA (2/2)

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

Conclusions

conclusively 2 formulas to reflect :

Quality = fulfillment of requirements *(ability / skills)* **x mind-set** *(want / behavior)*

QM = process focus *(effective & efficient processes)* **x risk based thinking** *(prevention)* **x PDCA-approach** *(continuous improvement)*

Your contact:

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I would be very happy to hear from you again.

If you leave me a message, I will aim to return within 24 hours.