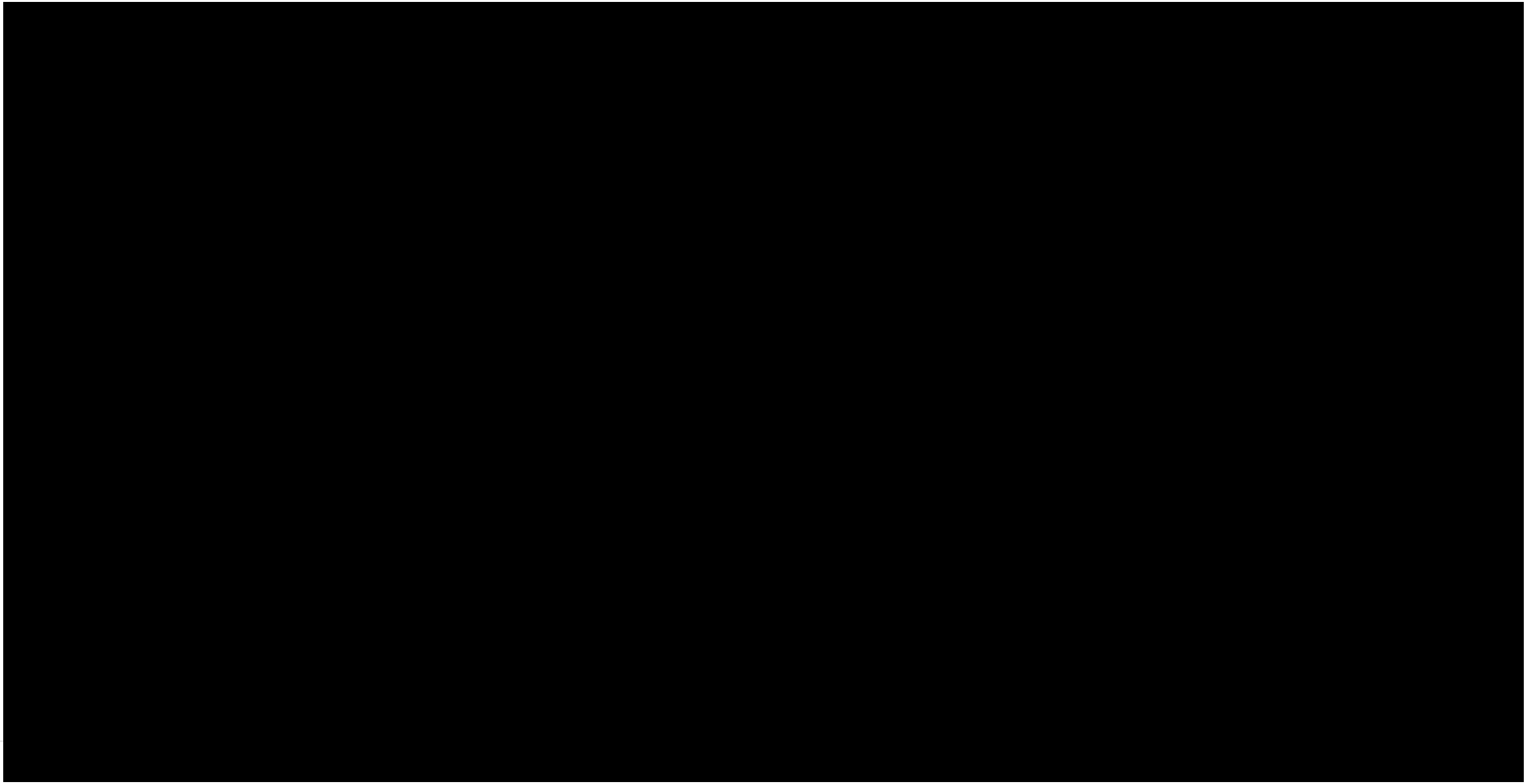

SMITHERS
QUALITY ASSESSMENTS

Introduction to Risk

Presenter: Kevin M. Gholston – CVG Strategy
July 9, 2015

SMITHERS
QUALITY ASSESSMENTS

Introduction to Risk Management

CVG STRATEGY

Training Program

- ISO 9001:2015 and Risk
- Implementation Options for Conformance
- Risk and Opportunities Register
- Our "Game of Risk"

ISO 9001:2015 Clauses

ISO 9001:2015 Clauses

9001:2015	9001:2008
Clause 1 - Scope	Clause 1 - Scope
Clause 2 - Normative references	Clause 2 - Normative references
Clause 3 - Terms and definitions	Clause 3 - Terms and definitions
Clause 4 - Context of the organization	Clause 4 - Quality management system
Clause 5 - Leadership	Clause 5 - Management responsibility
Clause 6 - Planning	
Clause 7 - Support	Clause 6 - Resource management
Clause 8 - Operation	Clause 7 - Product realization
Clause 9 - Performance evaluation	Clause 8 - Measurement, analysis & improvement
Clause 10 - Improvement	

ISO 9001:2015 Risk in the Clauses

- **Introduction -** concept of risk-based thinking (RBT) is explained
- **Clause 4 -** determine the risks which can affect its ability to meet these objectives
- **Clause 5 -** top management required to commit to ensuring Clause 4 is followed
- **Clause 6 -** take action to identify risks and opportunities

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ISO 9001:2015 Risk in the Clauses

- **Clause 8 -** implement processes to address risk
- **Clause 9 -** monitor, measure, analyze and evaluate the risks and opportunities
- **Clause 10 -** improve by responding to changes in risk

Concepts in ISO 9001:2015

- The concept of "risk" relates to the uncertainty of achieving such objectives
- The concept of "opportunity" relates to exceeding expectations and going beyond stated objectives

Risk based approach

Risk: Effect of uncertainty on an objective

Effect is a deviation from the expected – positive or negative.

Objectives can have different aspects and can apply at different levels.

Risk is often characterized to **potential** events and consequences

Risk may be a combo of the **consequences** of an event & the **likelihood** of occurrence.

Uncertainty is the **state of deficiency** of information understanding of an event

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What is "Risk Based" Thinking?

1. Something we all do automatically and often sub-consciously to get the best result.
2. The concept of risk has always been implicit in ISO 9001 (Preventative Action) – 9001:2015 makes it more explicit and built it into the QMS.
3. Ensures risk is considered from the beginning and throughout the process approach.
4. Makes preventive action (risk mitigation) part of strategic planning.
5. Risk is often thought of only in the negative sense. RBT can also help to identify opportunities (positive).

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ISO 9001:2015 & RBT

- The ISO 9001:2015 DIS has termed RBT for:

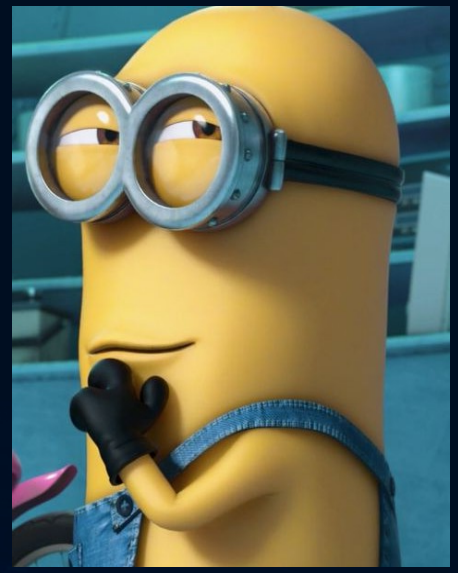
1. Establishment
2. Implementation
3. Maintenance
4. And continual improvement of the quality management system.

What do we do?

- ISO 9001:2015 RBT could…

(and I am not saying that it should)

…be demonstrated by one or more of the risk assessment tools in ISO 31010:2009



ISO 31010:2009

Table A.1 – Applicability of tools used for risk assessment

Tools and techniques	Risk assessment process					See Annex
	Risk Identification	Risk analysis			Risk evaluation	
		Consequence	Probability	Level of risk		
Brainstorming	SA[1)]	NA[2)]	NA	NA	NA	B 01
Structured or semi-structured interviews	SA	NA	NA	NA	NA	B 02
Delphi	SA	NA	NA	NA	NA	B 03
Check-lists	SA	NA	NA	NA	NA	B 04
Primary hazard analysis	SA	NA	NA	NA	NA	B 05
Hazard and operability studies (HAZOP)	SA	SA	A[3)]	A	A	B 06
Hazard Analysis and Critical Control Points (HACCP)	SA	SA	NA	NA	SA	B 07
Environmental risk assessment	SA	SA	SA	SA	SA	B 08
Structure « What if? » (SWIFT)	SA	SA	SA	SA	SA	B 09
Scenario analysis	SA	SA	A	A	A	B 10
Business impact analysis	A	SA	A	A	A	B 11
Root cause analysis	NA	SA	SA	SA	SA	B 12
Failure mode effect analysis	SA	SA	SA	SA	SA	B 13
Fault tree analysis	A	NA	SA	A	A	B 14

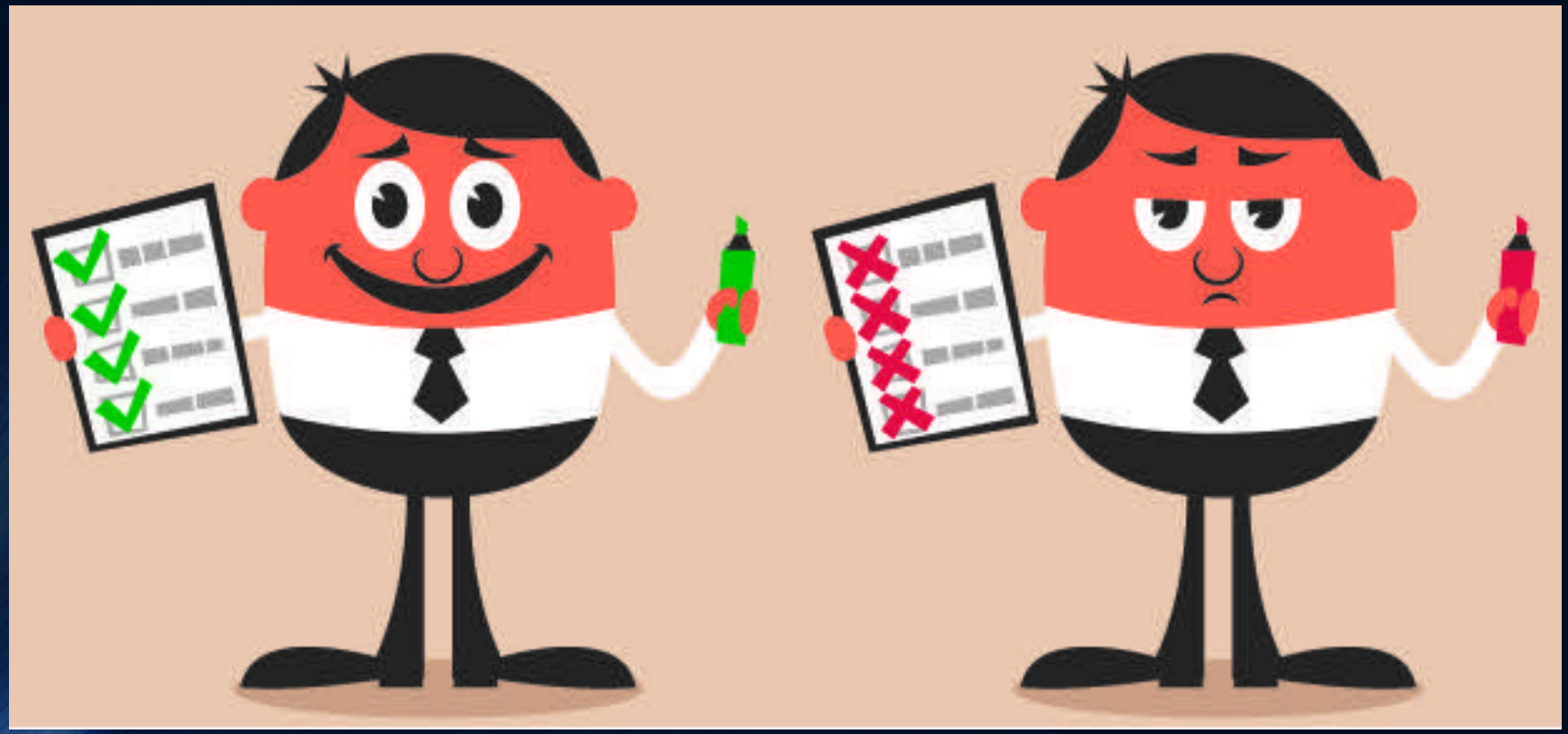
ISO 31010:2009

Table A.1 – Applicability of tools used for risk assessment

Tools and tec	Risk assessment process					Risk evaluation	See Annex
					risk		
Event tree analysis						NA	B 15
Cause and consequen						A	B 16
Cause-and-effect ana						NA	B 17
Layer protection analy						NA	B 18
Decision tree						A	B 19
Human reliability anal						A	B 20
Bow tie analysis						A	B 21
Reliability centred ma						SA	B 22
Sneak circuit analysis						NA	B 23
Markov analysis						NA	B 24
Monte Carlo simulatio						SA	B 25
Bayesian statistics an						SA	B 26
FN curves						SA	B 27
Risk indices						SA	B 28
Consequence/probability matrix	SA	SA	SA	SA		A	B 29
Cost/benefit analysis	A	SA	A	A		A	B 30
Multi-criteria decision analysis (MCDA)	A	SA	A	SA		A	B 31

Are structured interviews and brainstorming 9001:2015 requirements?

No, but would it be easier than a Markov analysis or Bayesian statistics?



Planning and considering risks

- ISO 9001:2015 takes a risk-based approach to the planning and implementation of your QMS, resulting in an appropriate and affordable level of quality.

- In this way, it ensures that the right people, processes, procedures and technologies are in place to achieve the intended results of the quality management system.

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What actions are required to plan for risks and opportunities in ISO9001:2015?

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

NO CRYSTAL BALL!

1. The new standard does not require the use of a risk registry.

2. However, a risk registry may be an ***effective way*** to demonstrate that the **risks** have been considered (evidence).

3. Other methods will be equally acceptable if all applicable **risks** are clearly identified.

4. ISO 9001:2015 DIS doesn't require a formal risk program.

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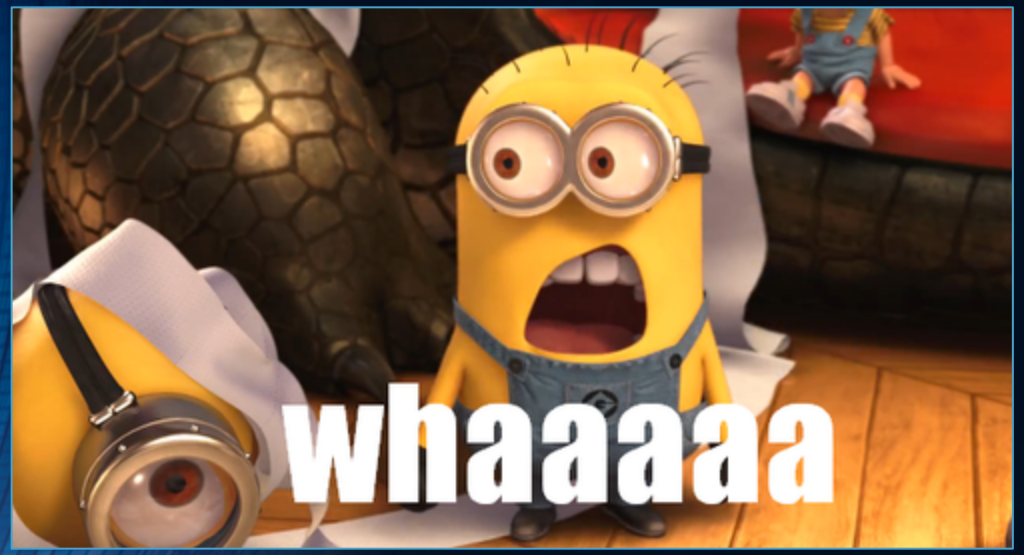
How will the Registration Auditors behave?



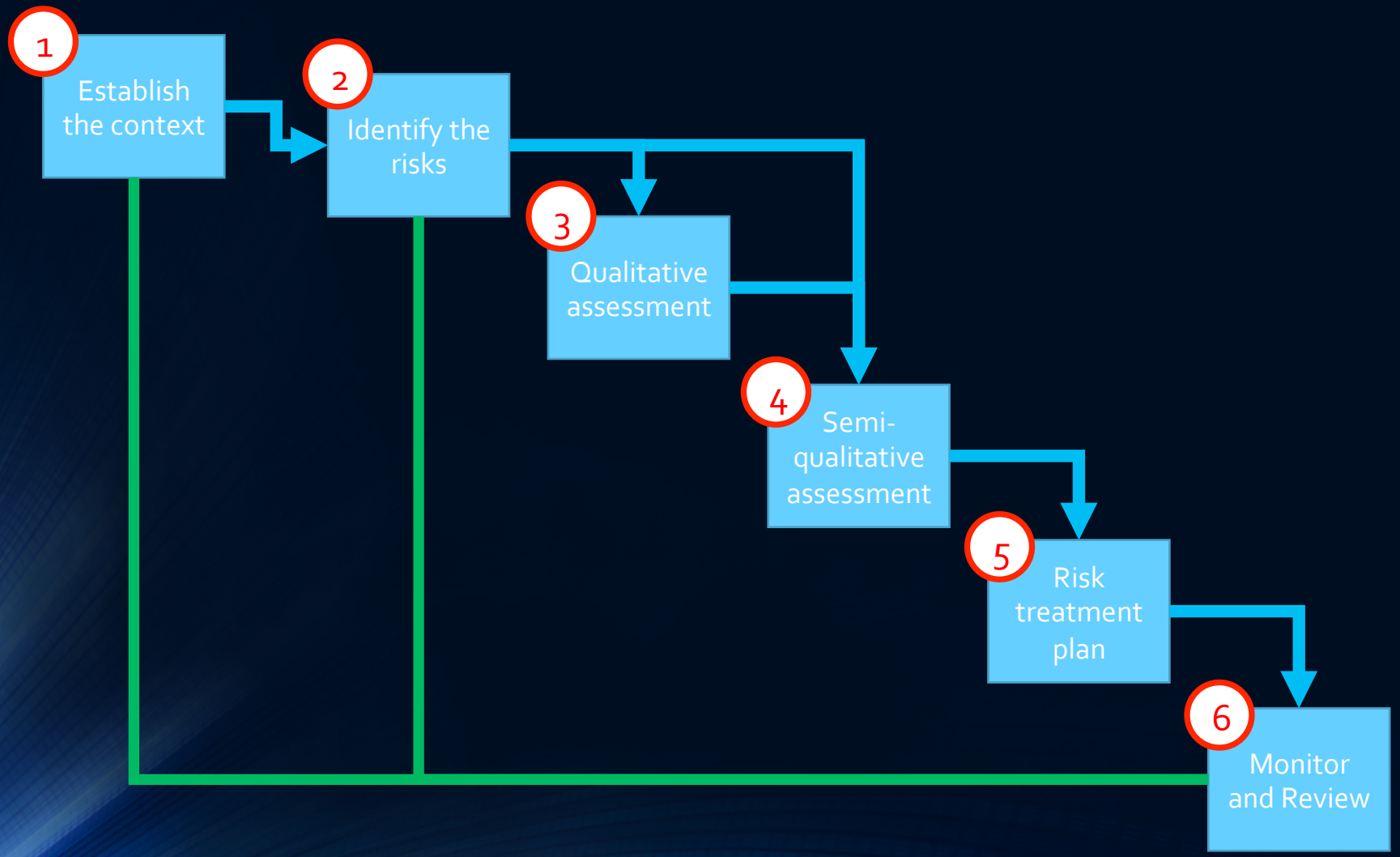
1. Report on non-conformances and corrective actions which would probably have been unnecessary with proper consideration of the risks
2. Highlight in their report any good practices seen in the application of risk-based thinking to the planning and consideration of quality processes
3. Highlight in their report any good practices seen in the application of risk-based thinking to the planning and consideration of quality processes

Why not use a Risk & Opportunity Register?

- (1) Establish **the context**
- (2) **Identify possible risks** to quality outputs
- (3) Carry out a **qualitative risk analysis** and risk evaluation
- (4) Extend this analysis to a **semi-quantitative analysis** used to assign a numerical risk factor (RF value) to each of the risks in order to determine the highest priority risks
- (5) Determining a **risk treatment plan**
- (6) **Monitoring** and reviewing the quality system processes to determine the effectiveness of the quality controls and identify as early as possible any new risks and opportunities

CV STRATEGY

Risks and Opportunities Register



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Risk Opportunity Register

Risk Identification		Qualitative Rating				Risk Treatment Plan		
Risk	Risk Category	Probability	Impact	Risk Score	Risk Ranking	Risk Response	Trigger	Risk Owner

Risk: The risk stated in a complete sentence which states the cause of the risk, the risk, and the effect that the risk causes to the project.
Risk Category: Categorization of risks by area of project affected, source of risk or other useful category.
Probability: The likelihood that a risk or opportunity will occur (on a scale from 0 to 10 with 10 being the highest).
Impact: The impact of the risk on the project if the risk occurs (scale from 0 to 10 with 10 being the highest).
Risk Score: Determined by multiplying probability and impact (scale from 0 to 100 with "+" being positive and "-" being negative.).
Risk Ranking: A priority list which is determined by the relative ranking of the risks (by their scores) within the project with the number one being the highest risk score.
Risk Response: The action which is to be taken if this risk occurs.
Trigger: Something which indicates that a risk is about to occur or has already occured.
Risk Owner: The person who the project manager assigns to watch for triggers, and manage the risk response if the risk occurs.

STEP 1: Establish the Context

- Context is “the business environment”
- It is about who you are as a company and what you do.

ISO 9001:2015 Clause 4.1

- Establish the external and internal organizational context in which the risk assessment is taking place;
- Specify the main objectives and outcomes that are uncertain and, therefore, represent a risk;
- Develop criteria against which the consequences and likelihoods of identified risks can be measured; and
- Define the key elements for structuring the risk assessment process.

STEP 1: Establish the Context

Internal:

- Context which can be facilitated by considering issues related to values, culture knowledge and performance of the organization
- Your own business requirements - not coming from the government or regulators or your customers

STEP 1: Establish the Context

External:

1. Criticality of your services to customers - what are the risks associated with failure?

2. Legal and regulatory requirements - consisting of legislation that the organization needs to adhere to such as intellectual property rights law, data privacy legislation, etc.

3. Contractual obligations - requirements from the customers normally stated in contract documents.

Minion Risk Context Statement

Risk Context Statement

External, Internal and Interested Parties		
1. Organization:	MINIONS, INC.	
2. Purpose:	To seek out and serve the most despicable master they can find	
3. Objectives:	Make money so that more Minions can be built	
4a. External context:	legal	No legal impact as they operate in the Artic
	technological	Velcro is important
	competitive	4 Companies worldwide manufacture Minions
	market	Children and Adults worldwide
	cultural	Speak Gibberish
	social	Friendly and non-confrontational
	economic	All about making more minions
	other	
4b. Internal context:	values	loyal yet childish and funny
	culture	Minionese
	knowledge	Uncontrollable craving for fruits and a strange obsession with butt jokes
	performance	Relentless

Minion Risk Context Statement

Risk Context Statement

5a. Interested parties	1.	Scarlet Overkill, President
	2.	Stuart
	3.	Kevin
	4.	Bob
	5.	
	6.	

5b. Requirements of interested parties:	**Interested party #1**	Universal Pictures
	Interested party #2	Illumination Entertainment
	Interested party #3	Steve Carell (Felonious Gru)
	Interested party #4	Russell Brand (Dr. Nefario)
	Interested party #5	Jason Segel (Vector)
	Interested party #6	

6. Objectives for the risk assessment:	Ensure that high quality minions are produced in high volume to support objective

7. Specific changes to criteria:	None are noted

Reference documents:	1.	Universal Pictures Contract with Minion, Inc.
	2.	ISO 9001:2015
	3.	Minions, Inc. QMS
	4.	

Compiler:	Date:	Reviewer:
Bazooka Dave	4-Jul-15	Felonious Gru

STEP 2: Risk identification

- Determination new risks and document in R&O
- Each risk is described in terms of:
  - what could happen
  - what that could lead to
  - causes of the risk
  - existing controls that could prevent, transfer or mitigate risk

Step 3: Qualitative Risk analysis & risk evaluation

- The systematic use of available information regarding:

1. Probability
2. Consequence
3. Exposure

Step 3: Qualitative Risk analysis & risk evaluation

- For each risk we would then:
- assess the effectiveness of the existing controls using a suitable effectiveness scale
- determine the consequences (**impact**) for each risk
- the likelihood of these consequences occurring
- and the potential exposure were the controls that we have in place to fail

Step 3: Qualitative Risk - Rating

PROBABILITY

Likelihood	Risk Level				
Almost certain 10	Medium 20	High 40	High 60	Extreme 80	Horrible 100
Likely 8	Medium 16	Medium 32	High 48	Extreme 64	Extreme 80
Possible 6	Low 12	Medium 24	High 36	High 48	Extreme 60
Unlikely 4	Low 8	Low 16	Medium 24	Medium 32	High 40
Rare 2	Low 4	Low 8	Medium 12	Medium 16	High 20
Consequence	Insignificant 2	Minor 4	Moderate 6	Major 8	Catastrophic 10

IMPACT

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Step 3: Qualitative Risk - Rating

PROBABILITY

Likelihood	Opportunity Level				
Almost certain 10	Medium 20	High 40	High 60	Wonderful 80	Tremendous 100
Likely 8	Medium 16	Medium 32	High 48	Wonderful 64	Wonderful 80
Possible 6	Low 12	Medium 24	High 36	High 48	Wonderful 60
Unlikely 4	Low 8	Low 16	Medium 24	Medium 32	High 40
Rare 2	Low 4	Low 8	Medium 12	Medium 16	High 20
Consequence	Insignificant 2	Minor 4	Moderate 6	Major 8	Fantastic 10

IMPACT

STEP 4: Semi-Quantitative risk assessment

- Qualitative analysis is used to determine the **probability** and **impact** of risks, however, by its nature and definition, lacks quantitative precision.
- Semi-quantitative measure of risk is a **scored estimate**
- All assessments are easily **compared** (same system)

STEP 4: Semi-Quantitative risk assessment

- **Scores** are applied to each component of risk
- Assess both the **consequence** (impact) and **likelihood** (probability) of the risk occurring
- To derive a **score** for the risks associated with each process analyzed
- Use risk scores to determine comparative **risk factors** associated with different processes to aid decision-making

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STEP 5: Risk Treatment

This step brainstorms options for treating the risk that fit the following categories:

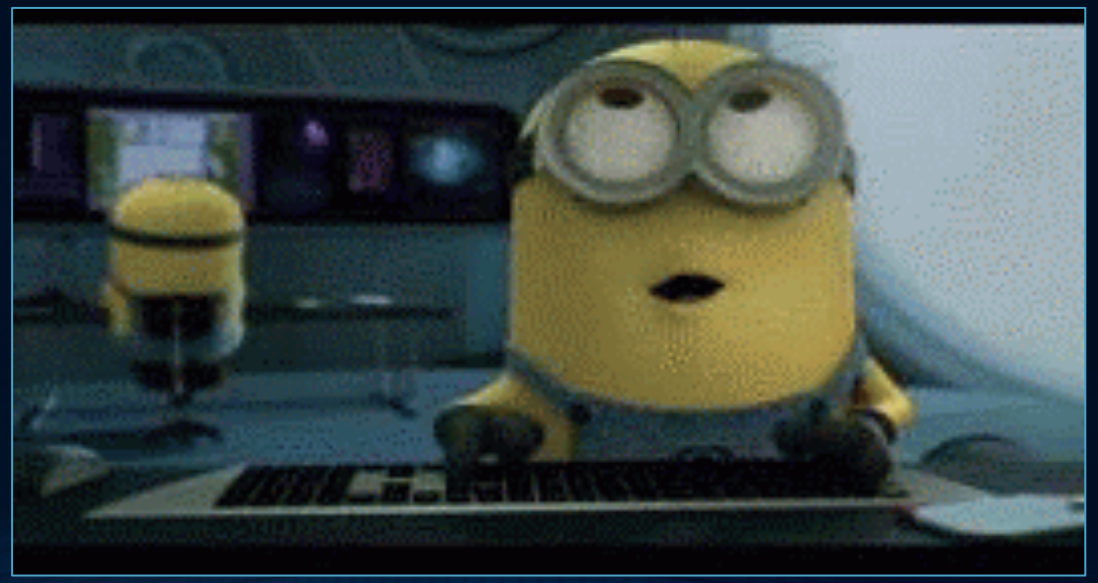
1. Avoiding or seeking the risk
2. Changing the likelihood
3. changing the consequences
4. Sharing the risk
5. Explicitly accepting the risk without further treatment

STEP 5. Risk Treatment

- The benefits and costs, advantages and disadvantages of each treatment option are taken into account.
- Where the benefits determined exceed the known/likely costs of action, treatment options are selected for implementation.

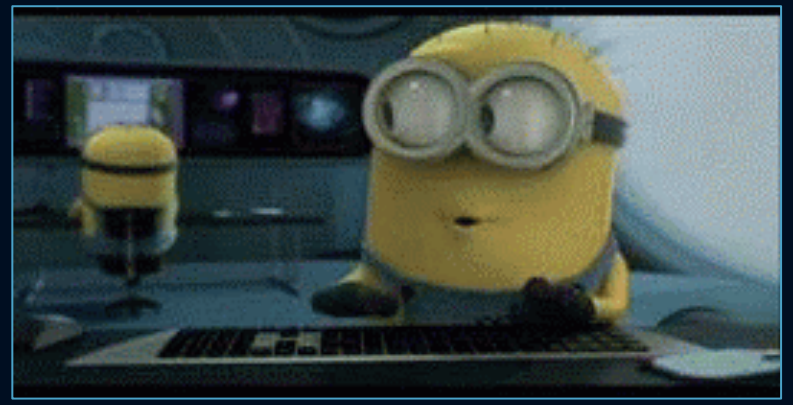
Step 6: Monitoring & review

- A monitor process is developed for each risk by the risk owners and each relevant control (control owners).
- Decisions are made about the time intervals at which the risks and controls will be reviewed.



Step 6: Monitoring & review

- A **monitoring process** will be put in place for each risk treatment plan under the direction of the relevant risk owners.
- **Progress will be monitored** in respect to the objectives of the risk treatment plan, and the **resulting successes and failures recorded**.
- Periodically, **assess whether new risks** are affecting or could affect quality processes and systems as part of the cycle of continuous quality process improvement



Risk and Opportunity Register

- CVG Strategy's recommendation (currently) to enable RBT
- Easy to implement
- Simple to demonstrate evidence of conformance
- But you must plug it in the rest of your upgraded QMS to make it effective…

Conclusion

- Questions and Answers?

Simulation – Our "Game of Risk"

CVG Strategy's "Risk" Simulation Game

The Rules

- A turn-based game for four players
- This room is divided into four companies:
  - Team I - Red
  - Team II - Glue
  - Team III - Green
  - Team IV - Yellow

CVG Strategy's "Risk" Simulation Game

The Rules

- Object of Game:

1. Maximize number of employees
2. Gain new markets (territory) when possible by defeating competition

Organize Teams

Moderator

TEAM I.
RED

General Manager - 1
Risk Review Team – 5
Employees - 30

TEAM II.
BLUE

General Manager - 1
Risk Review Team – 5
Employees - 30

TEAM III.
GREEN

General Manager - 1
Risk Review Team – 5
Employees - 30

TEAM IV.
YELLOW

General Manager - 1
Risk Review Team – 5
Employees - 30

CVG Strategy's "Risk" Simulation Game

The Rules

- Each Team (Company) has management and employees
- General Manager (hat) ***[SELECT NOW]***
- Risk Team (to process Risk Cards in R&O Register)

CVG Strategy's "Risk" Simulation Game

Risk Team

1. Operations
2. Quality (responsible for R&O Register)
3. Purchasing
4. Sales
5. Human Resources (responsible for headcount)

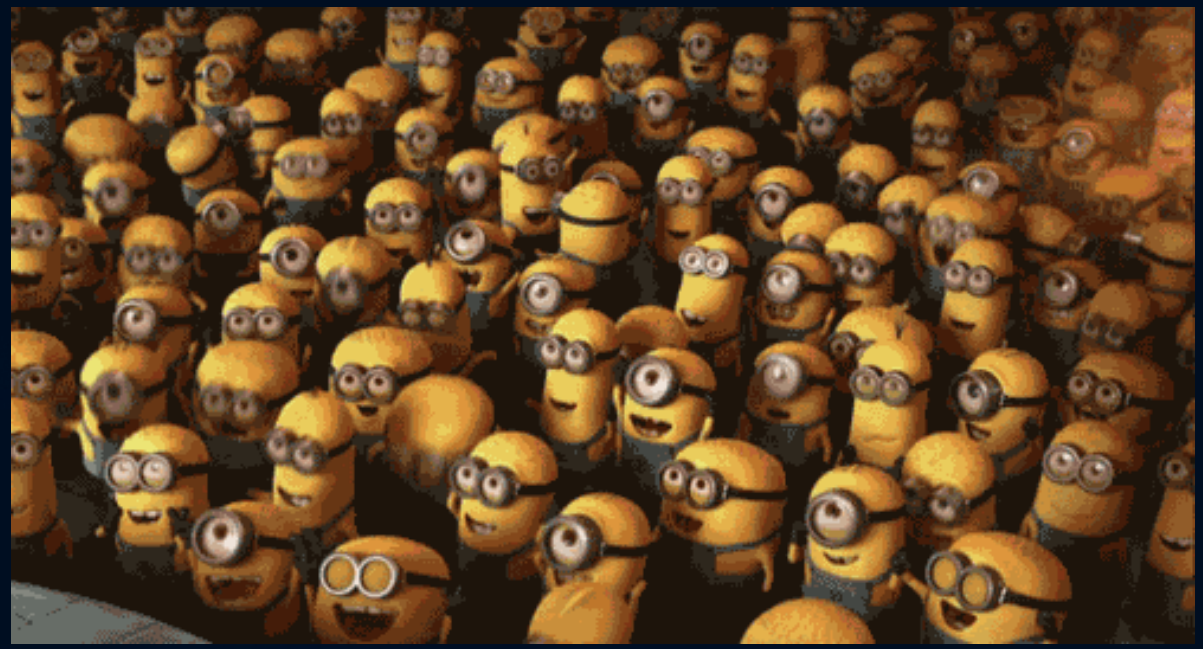
[SELECT NOW]

CVG Strategy's "Risk" Simulation Game

The Rules

- Who are the employees?

THE REST OF YOU!



CVG Strategy's "Risk" Simulation Game

The Rules

- Standard Equipment:
- Five dice in two colors: three black for attacker and two red for defender – to be rolled by General Manager
- R&O Register – to be maintained by Quality
- Risk Cards (electronic on-screen)

CVG Strategy's "Risk" Simulation Game

The Rules

- Like the game – each team (company) starts with an initial and equal deployment of employees
- The territory (map) is the room
- Risk Cards are selected, market attacks planned, dice are rolled

CVG Strategy's "Risk" Simulation Game

Game Cycle:

1. Select a Risk Card
2. Risk Team to process Risk or Opportunity (90 seconds)
3. General Manager to deploy employees and attack new markets

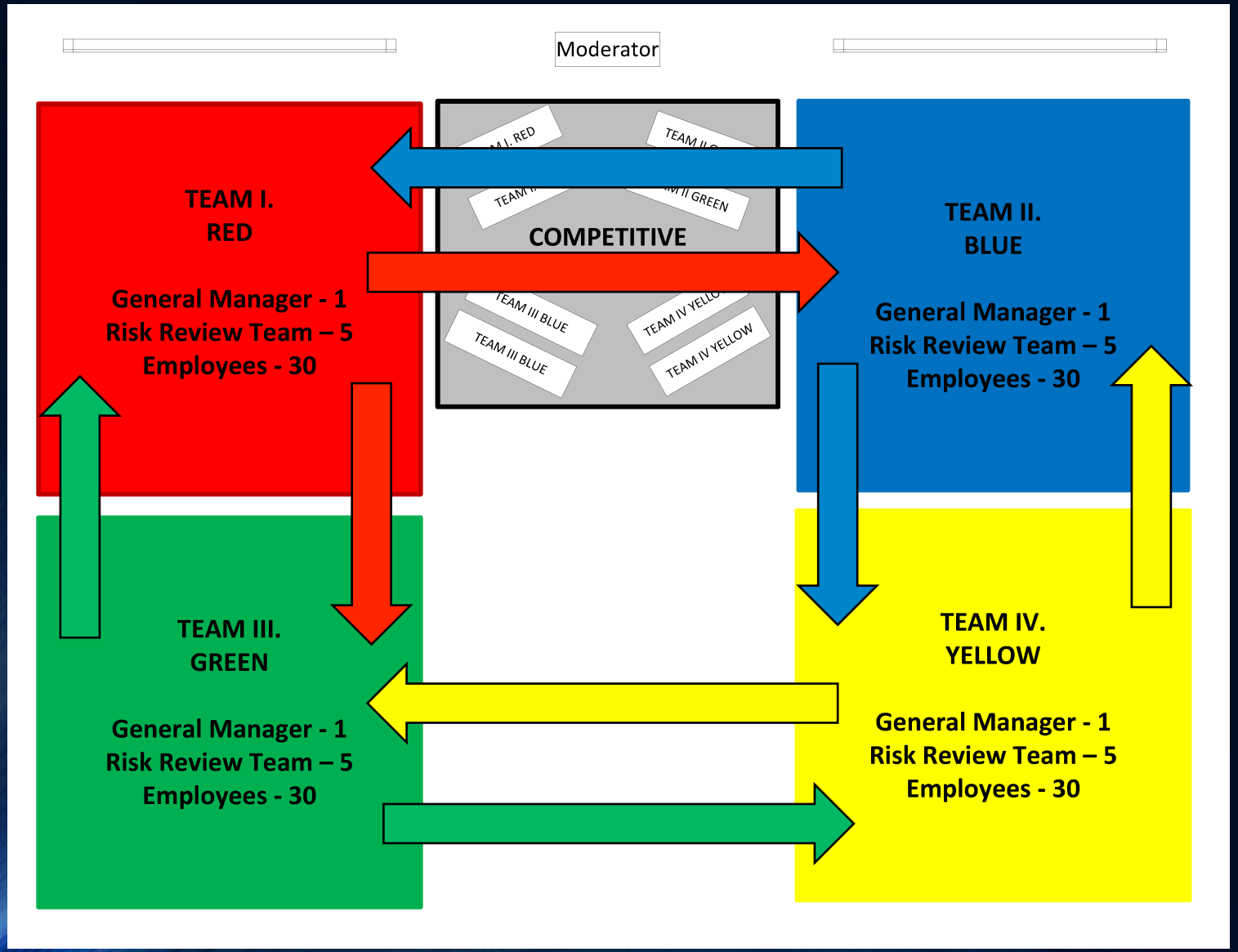
1. Select a Risk Card

- The GM will select a Risk Card
- Quality will enter into R&O Register

2. Risk Team to process Risk or Opportunity

- Assessment to be process in 90 seconds
- Risk Team to discuss pros and cons of qualitative risk assessment
- Quality to record data in R&O Register
- Based on Risk Team Score as compared to CVG Strategy's Score – Results (impact) to be applied to Team

3.General Manager to deploy employees



- Attacking Employees to move to center of room
- Defenders to face them there

DICE ROLL

- Attacker uses 3 dice & 25% of employees minimum
- Defender must provide 1:2 for one dice (minimum)
- Defender must provide 1:1 for two dice

DICE ROLL

- If any Attacker dice are > Defender, the Defender loses all defending employees
- If any Attacker dice = Defender, Attacker loses half attacking employees, may roll again or stop attack
- If any Defender dice > any Attacker dice, Attacker loses all attacking employees

Additional Rules

- If Defender loses all employees (only management is left), Attacker gains them as employees and takes over market (territory)
- Attacker may then deploy employees freely into new market

Additional Rules

- If any company (team) adds more employees than exist, they will receive a Minion Paddle which will represent 5 employees
- Human Resources must keep accurate count of employees
- Retired employees to move to back of room and will be called by HR when re-hired

1. Risk Card Selection

	A	B	C	D	E
1	• Risk	• Risk	• Risk	• Risk	• Risk
2	• Risk	• Risk	• Risk	• Risk	• Risk
3	• Risk	• Risk	• Risk	• Risk	• Risk
4	• Risk	• Risk	• Risk	• Risk	• Risk
5	• Risk	• Risk	• Risk	• Risk	• Risk
6	• Risk	• Risk	• Risk	• Risk	• Risk
7	• Risk	• Risk	• Risk	• Risk	• Risk

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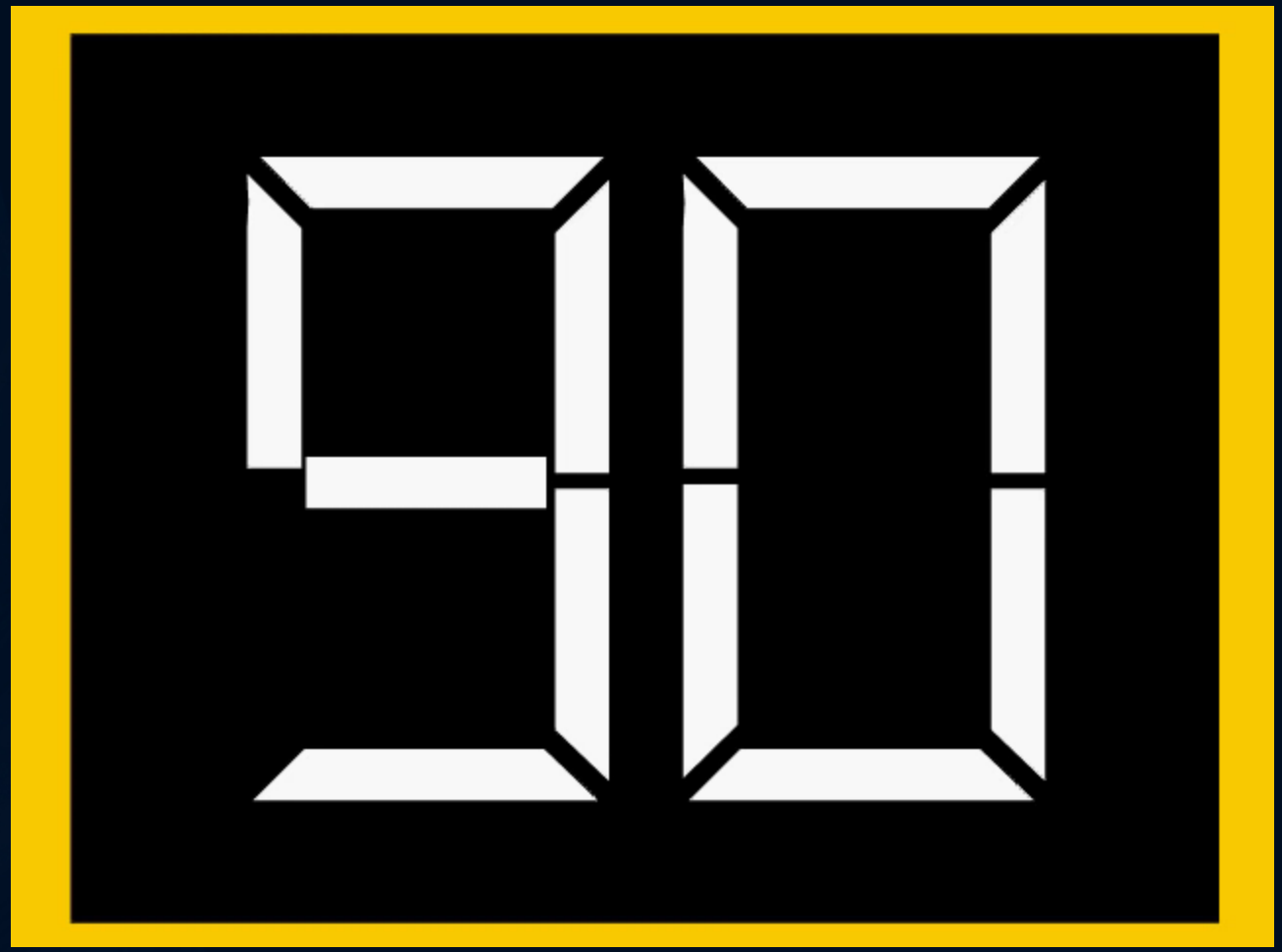
2. RISK & OPPORTUNITY ANALYSIS
90 SECONDS



3. GM to Deploy Attack

- Deploy
- Roll Dice
- Determine who wins and who loses

THANK YOU FOR THE OPPORTUNITY TO SPEND SOME TIME WITH YOU.

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