

FARIP (Facility Risk Profile)

...or how to eat the EHS risk management elephant

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BUSINESSEUROPE, Brussels



Johnson-Johnson

Agenda

- 1. Introduction
- 2. Goals of the FARIP project
- 3. Learn about FARIP Tool / Process
- 4. Learnings

Introduction



Our Company

- The world's premier consumer health company
- The world's largest and most diverse medical devices and diagnostics company
- The world's fourth-largest biologics company
- The world's seventh-largest pharmaceuticals company

250 operating companies
57 countries
119.000 people
HQ, New Brunswick, NJ, USA

Total Sales: \$ 63.7 billion Research: \$ 7.6 billion

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and faithers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices.

Customers' orders must be serviced promptly and accurately.

Our suppliers and distributors must have an apportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe, We must be mindful of ways to help our employees fulfill their family responsibilities.

Employees must feel fee to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well.

We must be good citizens — support good works and charities and bear our fair share of taxes.

We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders.
Business must make a sound profit.
We must experiment with new ideas.
Research must be carried on, innovative programs developed and mistakes paid for.
New equipment must be purchased, new facilities provided and new products launched.
Reserves must be created to provide for adverse times.
When we operate according to these principles, the stockholders should realize a fair return.

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Introduction

Risk Assessments...

within Johnson & Johnson within Janssen Pharmaceutica

- A long history of doing risk asessments
- High diversity of risks within our group of companies
- From very simple to very complex operations & activities
- Operating almost in all countries in the world
- EHS as important business imperative
- Strong EHS record
- Risk assessments integrated into our operations

Context

- Business reality today... challenges like cutting costs and increasing profits, economic pressure, regulatory obligations...
- Need for efficiency, quality, competitiveness, sustainability...
- Quality of life... safe and healthy workplaces, environmental awareness...

Context

Explosion and fire at the BP Texas City Refinery

"BP Senior executives... (conclusions of investigation report)

- Focused mostly personal safety performance, but not process safety...
- Did not provide adequate resources to prevent major accidents...
- Did not create a learning culture...
- Oversight was ineffective..."



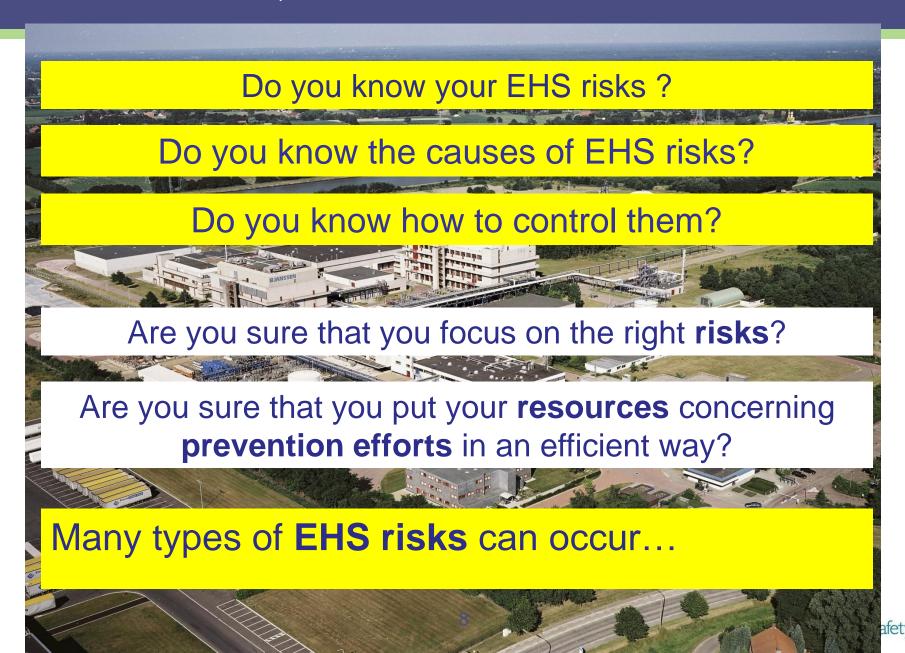
BP Texas City Managers did not create an

Environment Health & Safety

Goals

- Giving answers on current business needs
 - Improve performance
 - New things
 - Not increasing the effort
- Bring new added value to the current MAARS process
 - Comply with current MAARS Standards (basic)
 - FARIP as input for risk analysis process
- Next step in risk-based decision making

What is FARIP, FACILITY RISK PROFILING?



What is FARIP, FACILITY RISK PROFILING?



FARIP is...

- Facility Risk Profiling
- Making a risk profile for environmental, health and safety risks for a facility, business unit, unit, activity...

FARIP will enable you to...

- Evaluate, understand and see your EHS risks
- Set priorities & focus resources

FARIP as part of the business model

Done by the business, supported by EHS



A project in different steps...

Phase 1:

- VOC
- Development of FARIP methodology
- Pilots of FARIP: Cashel, Val-de-Reuil, Titusville

2007

Phase 2:

- Finalise methodology & development of tools
- Pilots of FARIP: Geel, Puebla

2008

Phase 3:

Implementation of FARIP within GPSG



FARIP... a methodology in several steps

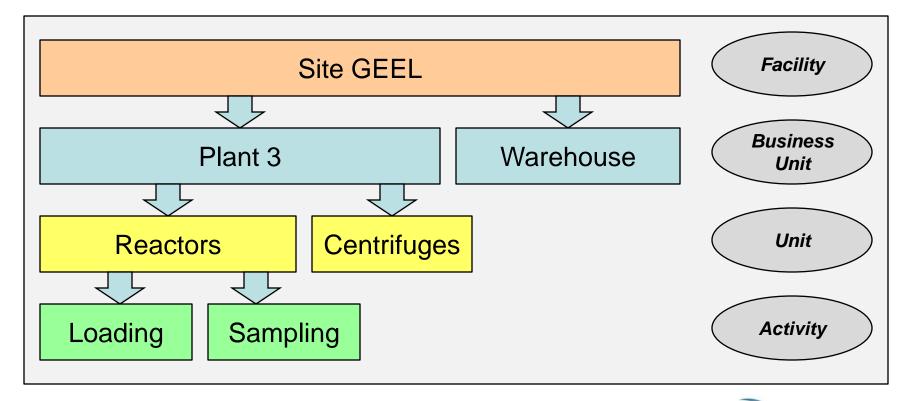
- 1. Split up the facility into functional groups & activities
- 2. Evaluate which EHS aspects will be evaluated on which level
- 3. Identify potential risk scenario's per EHS aspects
- 4. Do <u>risk evaluations</u> on your potential risk scenario and identify critical control measures in place
- 5. Identify GAP's & define actions
- 6. Generate <u>risk profiles</u>



How to organise a FARIP exercise?

- Set up different FARIP teams for the activities you want to profile
- Multidisciplinary
- Familiar with the specific activities
- Participative
- All levels in the organisation
- FARIP Coach
- Meeting room exercise

1. Split up your facility in different groups & activities



2. Evaluate which EHS aspects will be evaluated on which level

- Standard list of 27 EHS Aspects
 - 7 linked to environmental aspects
 - 20 linked to health & safety aspects
- All aspects have been linked to the current MAARS Chapters

Environmental (7)	Health & Safety (20)	
Water, Air, Noise, Light, Waste, Resource Consumption, Soil	Machines, Falling, Chemical Substances Exposure, Fire Explosion and Uncontrolled Chemical Reactions, Ergonomics, Moving and Powered Industrial	onment Health & Safet

Vohiclos...

2. Evaluate which EHS aspects will be evaluated on which level (example)

Aspects Risk for Noise Pollution **Facility** Site GEEL **Business** Risk for Water Pollution Plant 3 Warehouse Unit Risk related to Machines Unit Reactors Centrifuges Risk for Chemical Activity Loading Sampling Exposure

Examples of EHS

3. Identify <u>potential risk scenario's</u> per EHS aspect

• Example of an EHS aspect on the level of "Warehouse": "Risks related to moving and powered industrial vehiciles"



While driving in the warehouse, the lift truck hits a person with fracture of a leg as result.

• Hazard: driving lift truck

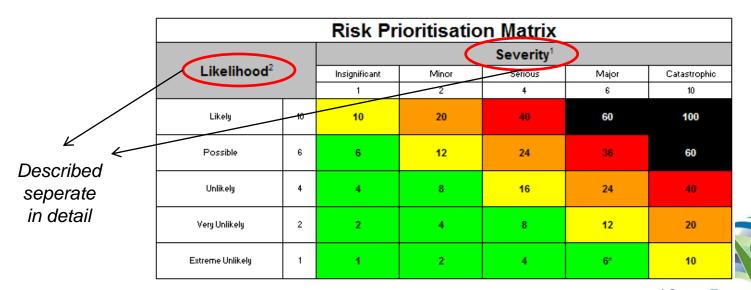
• Exposure group: walking persons in the warehouse

• Event: collision between lift truck and person

Damage: fracture of a leg

4. Do <u>risk evaluations</u> on your potential risk scenario and <u>identify critical control measures</u> in place

- Start to evaluate the "potential risk" (no critical control measures in place)
- Define severity & likelihood with FARIP risk matrix



4. Do <u>risk evaluations</u> on your potential risk scenario (see example)

- Define severity: "Fracture" = Score 4
- Define likelihood: "Possible" = Score 6
- → POTENTIAL RISK SCORE = 24

Risk Prioritisation Matrix								
Likelihood ²		Severity ¹						
		Insignificant	Minor	Serious	Major	Catastrophic		
		1	2		6	10		
Likely	10	10	20	4 0	60	100		
Possible	6	8	12 >	24	36	60		
Unlikely	4	4	8	16	24	40		
Very Unlikely	2	2	4	8	12	20		
Extreme Unlikely	1	1	2	4	6*	10		

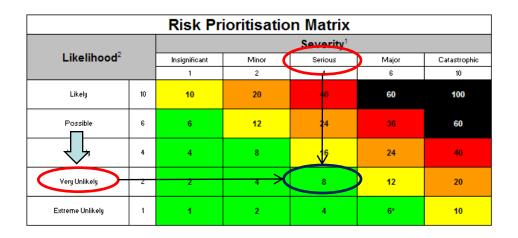


- 4. Do risk evaluations on your potential risk scenario and identify <u>critical control measures</u> in place (example)
 - Critical control measures to avoid accidents like hitting a person with a lift truck:
 - Training of lift truck drivers
 - Walking corridors for pedestrians
 - Instructions:
 - Looking into mirrors
 - Using the horn
 - •

4. Do <u>risk evaluations</u> on your potential risk scenario (with critical control measures)

- Evaluation of actual risk (with control measures in place)
 - Severity is still the same: "Fracture" = Score 4
 - Likelihood reduced to "Very unlikely" = Score 2

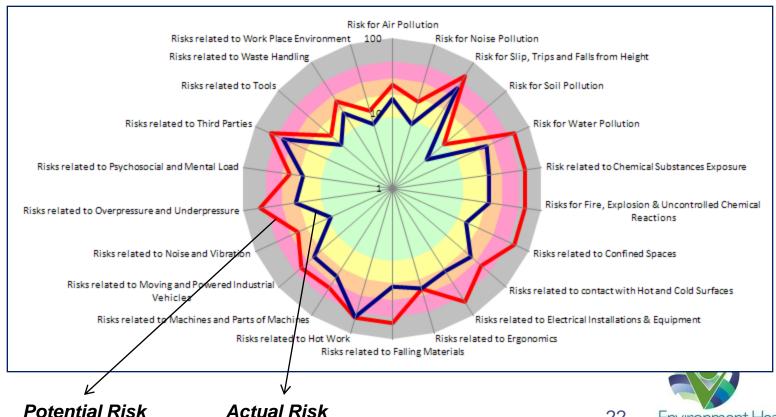
→ ACTUAL RISK SCORE = 8





6. Generate risk profiles

- Different formats are possible
- To generate by "one-click" out of FARIP Tool (xls)



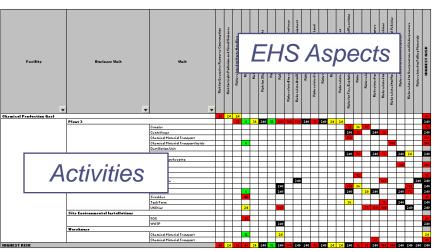
Important concept in the methodology:

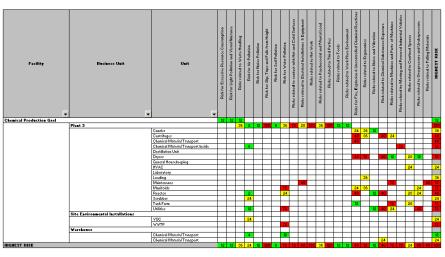
- Potential risk (overview)
- Actual risk (overview)

POTENTIAL RISK PROFILE



ACTUAL RISK PROFILE





To assure <u>critical control measures</u> stay in place for high potential risks

To <u>improve</u> continuously, but in a cost effective way

FARIP...conclusions

Several positive effects!

- More awareness of existing EHS risks
- Educational effect: during the FARIP exercise, participants exchange information and learn from each about EHS risks and how to control them
- Can replace the register with the aspect/impact analysis for ISO 14001
- As input for identifying risk priority chapter for MAARS
- FARIP will not replace (detailed) existing risk analyses (f.e. EJA, HAZOP, PHA...)
- FARIP will help you in comparing E-H-S risks, setting the right priorities in order to make the right decision

FARIP...conclusions

Critical Success Factors

- Commitment of management
- The right people in the FARIP Team (knowledge, experience)
- Multidisciplinary Team (supervisor, manager, EHS)
- Good communication before, during and after FARIP process
- FARIP must become a dynamic tool, repeated in time

FARIP

Conclusions

- Methodology will be implemented in all sites of J&J's Pharma Business
- FARIP, a methodology to create high level EHS risk profiles
- A management decision tool to set priorities and to focus on the right 'issues'
- We want to involve all levels of the organisation in doing risk assessments
- Change behavior and increase risk awareness

Questions?