Do you have a Fatality Risk Blind Spot ?

CBIA 2017
Safety & Health
Conference

alliance
An OSHA Cooperative Program

David Eherts PhD CIH
Vice President EHS
For CBIA
May 2017

Allergan

YOU'VE PROBABLY HEARD OF OUR PRODUCTS

Aesthetics & dermatology	Juvéderm VOLUMA™ XC, BOTOX® Cosmetic, Latisse® (bimatoprost ophthalmic solution) 0.03%, kybella™ (deoxycholic acid) injection, SkinMedica™, Natrelle®, Juvéderm VOLBELLA® WITH LIDOCAINE, Juvéderm ULTRA XC, NEW Aczone® (dapsone) gel, 7.5%, earfold™, VISTABEL® Botulinumtoxin Typ A, belkyra™ deoxycholic acid injection
Central nervous system	BOTOX® Botulinum Toxin Type A, Namenda XR® (memantine HCl) extended release capsules, Namzaric® (memantine HCl extended release and donepezil HCl capsules, Fetzima® levomilnacipran ER capsules, Viibryd® vilazodone HCl, Saphris® (asenapine) sublingual tablets 5 and 10 mg, Vraylar® (cariprazine) capsules
Eye care	Restasis® (Cyclosporine Ophthalmic Emulsion) 0.05%, Combigan® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%, LUMIGAN® 0.01% (bimatoprost ophthalmic solution) 0.01%, Ozurdex® (dexamethasone intravitreal implant) 0.7 mg, Refresh Optive®, optive® FAMILY, GANfort® (bimatoprost/timolol ophthalmic solution) 0.03%/0.5%, XEN® GEL IMPLANT
Women's health	Lo Loestrin Fe® (norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets) 1 mg/10 mcg and 10 mcg, ESTRACE® CREAM (estradiol vaginal cream, USP, 0.01%), Liletta® (levonorgestrel-releasing intrauterine system) 52 mg, diafert, Levosert®
Urology	BOTOX®, RAPAFLO® 8 mg (silodosin) capsules
GI	Viberzi® (eluxadoline) tablets C 75 mg • 100 mg, Linzess®, Asacol® (mesalamine) delayed-release tablets 400 mg per tablet, Delzicol® (mesalamine) 400 mg delayed-release capsules, Zenpep® (pancrelipase) Delayed-Release Capsules, PYLERA® CAPSULES (bismuth subcitrate potassium, metronidazole, tetracycline HCl), EZICLEN, Panzytrat® ok (pancreatin), Constella® Linaclotide
Anti-infectives	Avycaz® ceftazidime-avibactam for injection, Teflaro® (ceftaroline fosamil) for injection 600 mg • 400 mg, Dalvance® (dalbavancin) for injection
Other (incl. cardiovascular)	NEW Byvalson®, Bystolic® (nebivolol) tablets 2.5 mg • 5 mg • 10 mg • 20 mg

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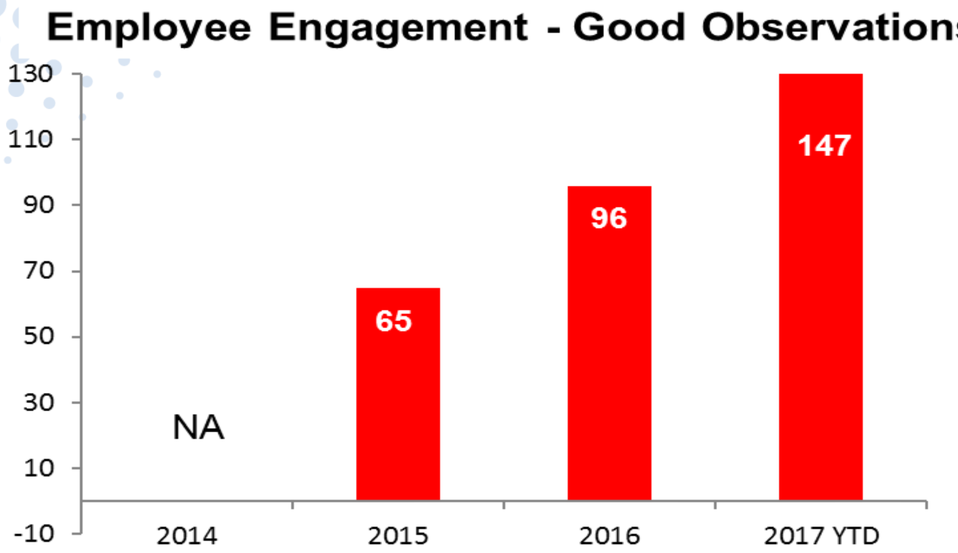
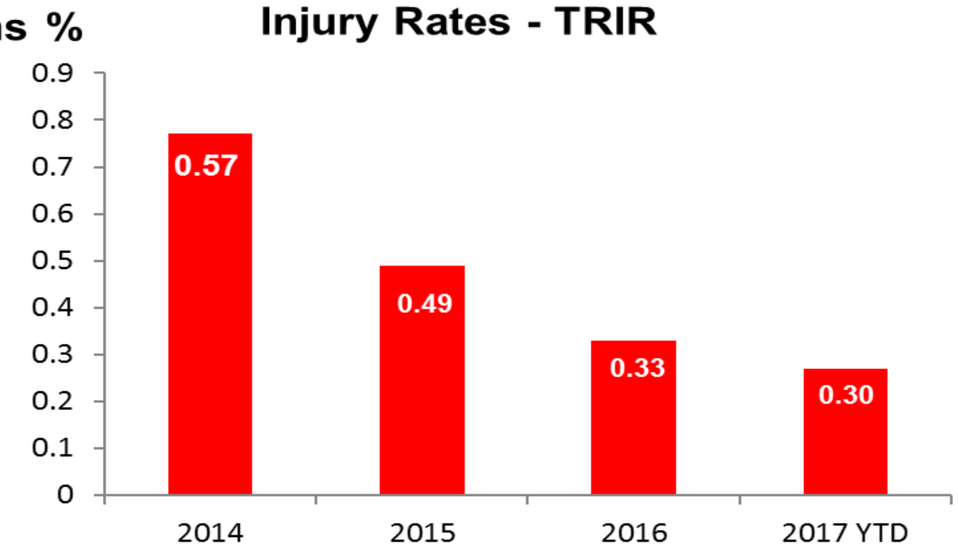
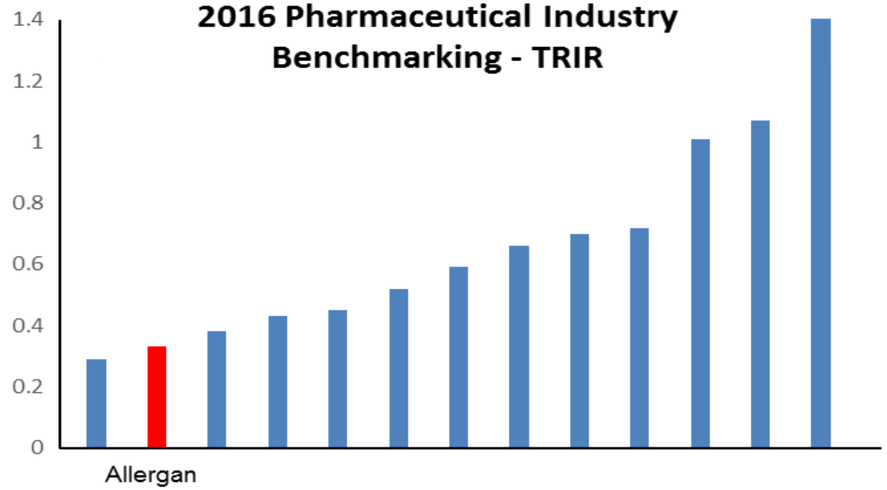
A LITTLE BIT ABOUT ALLERGAN EHS

Environment, Health and Safety Results

Engaged/Involved Employees have > 95% correlation to decreasing Injury Rates







Industry Leadership in EHS

Injury Rates among the best

Most progressive programs

GO's, Gembas, Learning teams…

Allergan being asked for benchmarking

Alcoa, Amgen, Lockheed…

Sustainability Leadership also

Announced at Davos

HOW WE GOT HERE

LEARNING OBJECTIVES

1. Introduce Human and Organizational Performance concepts relating to SIF prevention

    Create a paradigm shift in thinking about Safety

2. Demonstrate how HOP Theory has influenced these EHS programs at Allergan

    R2P

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HOW DOES OUR COMPANY DEFINE “SAFETY”?

Safety is not the absence of accidents.

Safety is the presence of defenses.

HE'S NEVER FALLEN OFF THE ROOF – IS IT THEREFORE SAFE?

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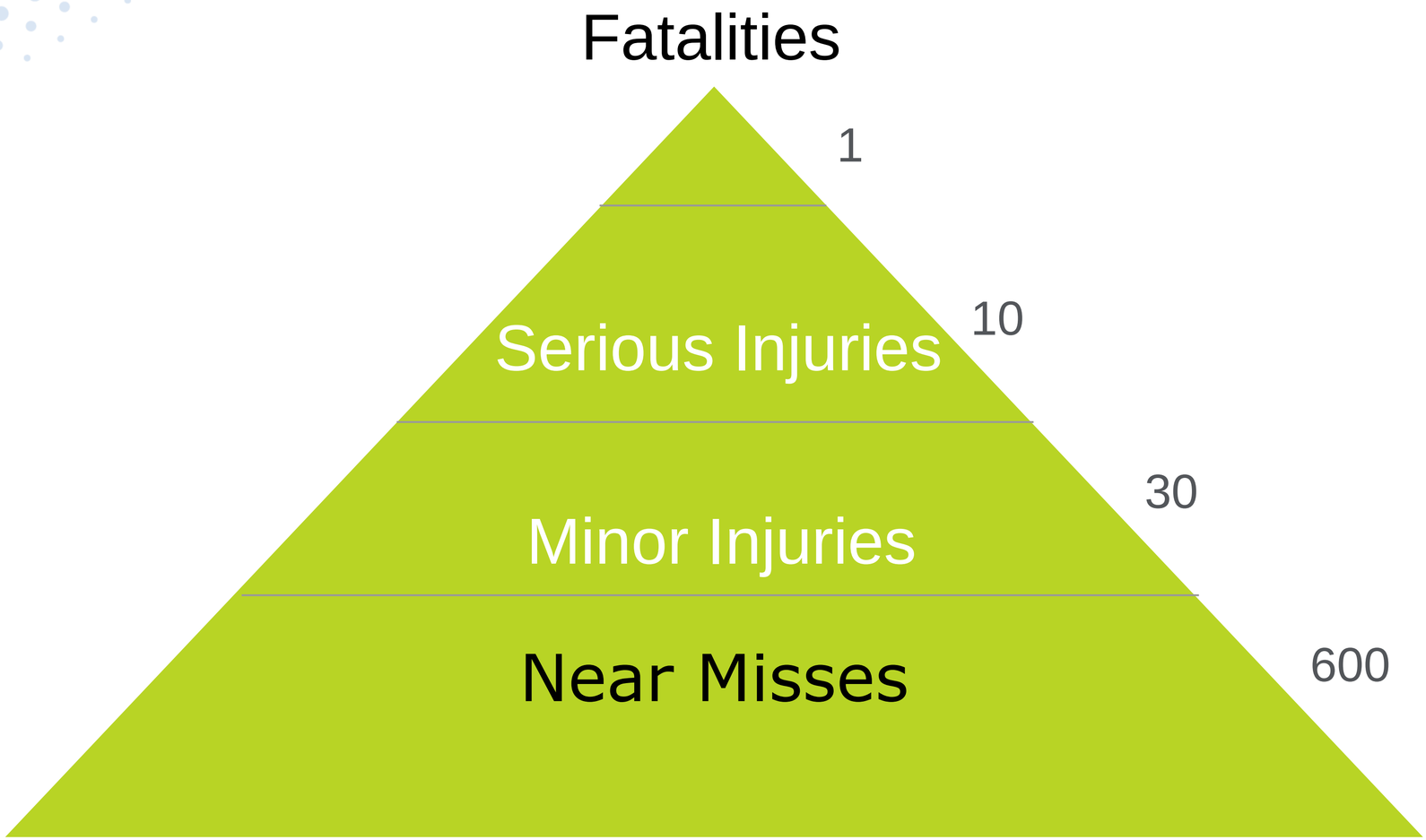
IS ZERO THE RIGHT TARGET?

Zero as a metric literally measures nothing and you can't prevent failure based on knowing nothing

Todd Conklin

Allergan

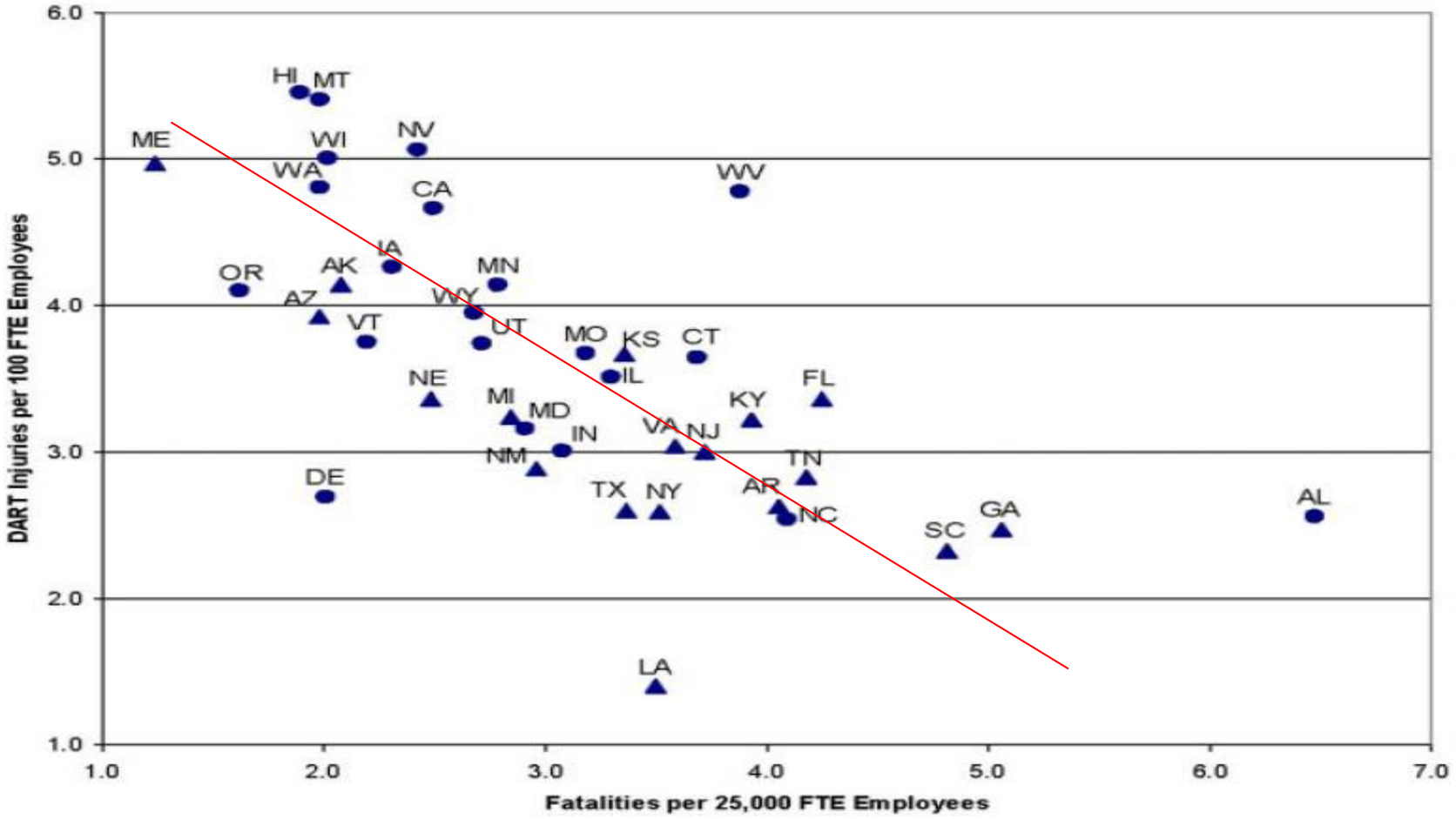
THE HEINRICH PYRAMID



Herbert William Heinrich, Industrial Accident Prevention, A Scientific Approach, 1931

IS THE HEINRICH PYRAMID CORRECT?

The lower the incident rate, the higher the fatality rate



- State DART rate vs. fatalities graphic
  - –2013 RAND Study Am J Ind Med
- Corroborating Studies
  - –Finnish Construction and manufacturing study 1977-1991
  - –Aviation passenger mortality risk 2000
  - –Occupational Injury Statistics in Korea 2011
    - Injury rate 1/5 EU rate fatality rate 5 x's EUs

Disasters don't happen because someone drops a pipe on his foot or bumps his head. They result from flawed ways of doing business that allow risks to accumulate.

(Elkind and Whitford 2011, p. 7)

IS ZERO THE RIGHT TARGET?

The difference between a safe and unsafe organization lies not in how many incidents it has,

but in how it deals with the incidents that it has people report.

Sidney Dekker

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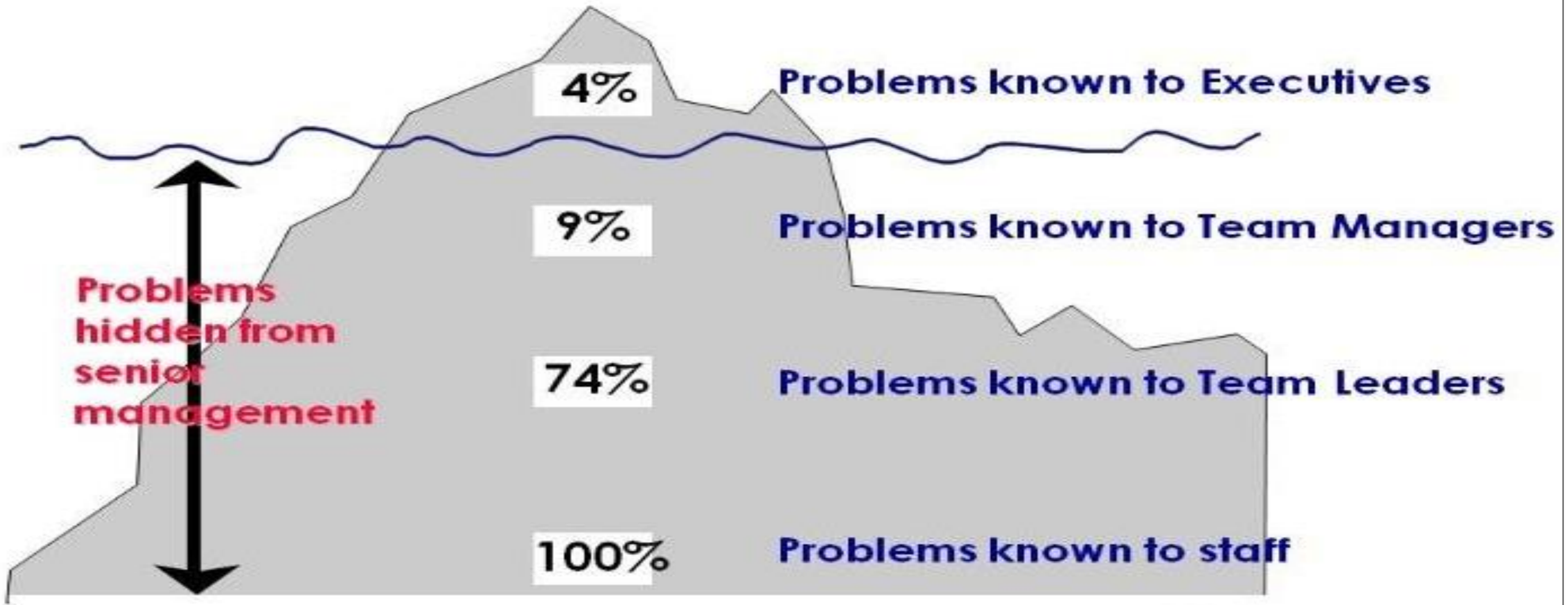
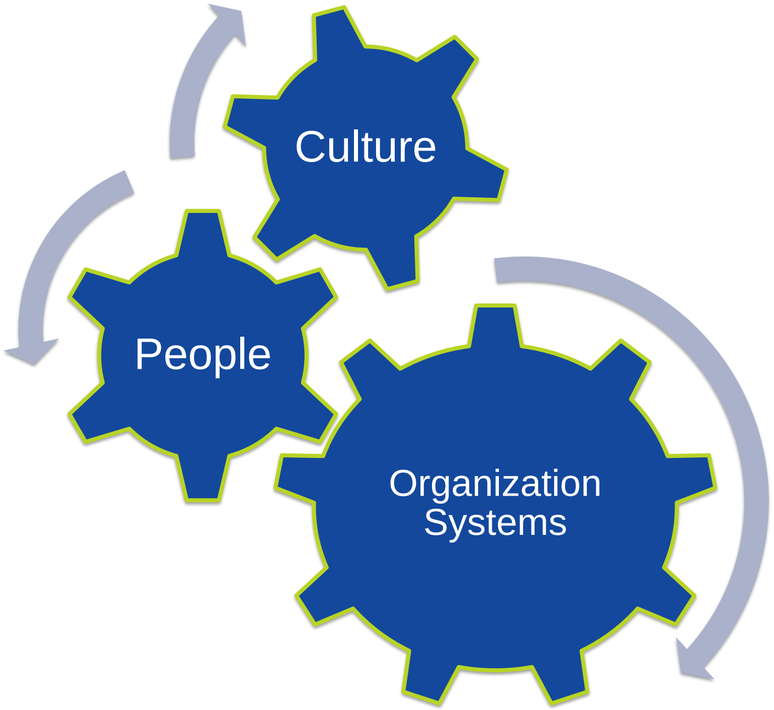
The Iceberg Of Ignorance



Adapted from
"Quality Improvement and TQC Management at Calsonic in Japan and Overseas"
Sydney Yoshida

HUMAN AND ORGANIZATIONAL PERFORMANCE



HOP seeks to understand how humans perform in complex organizational systems so we can build system defenses that are more error tolerant

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ERROR TOLERANCE

If we focus on preventing human error, we design ideal systems that assume successful outcomes but typically fail when errors occur

OR

Do we design systems that assume errors will occur but still typically result in successful outcomes

Focus on Systems

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ROBUST SYSTEMS

Fragile: Non-Robust

Stable: Non-Robust

Resilient: Robust

Conklin

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KEY PRINCIPLES OF HUMAN & ORGANIZATIONAL PERFORMANCE

1. **People are fallible, and even the best make mistakes**
2. **Error-likely situations are predictable, manageable, and preventable.**
3. **Individual behavior is influenced by organizational processes and values**
4. **Management's response to failure matters**
5. **The way to prevent incidents is by learning**

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PEOPLE ARE FALLIBLE AND EVEN THE BEST MAKE MISTAKES:

How many times does the uppercase or lowercase letter“F”appear in the following sentence?

Finished files are the result of years of scientific study combined with the experience of many years.

HUMAN LIMITATIONS

"Mistakes arise directly from the way the mind handles information, not through stupidity or carelessness."

-Edward de Bono PhD

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THE FAST BRAIN AND THE SLOW BRAIN

Slow Brain – Analytical thoughtful actions

Fast Brain – “habitual/reactive/without thinking”
Our actions are primarily directed by the fast brain

BRAIN-CENTERED HAZARDS: RISKS & REMEDIES
Susan L. Koen, Ph.D.

What if these brain-centered hazards are exacerbated by the fact that critical organizational elements—including work environments, technological interfaces, operating procedures, work schedules and even work cultures—**are not aligned with how the human brain actually works?**

Susan L. Koen, Ph.D.

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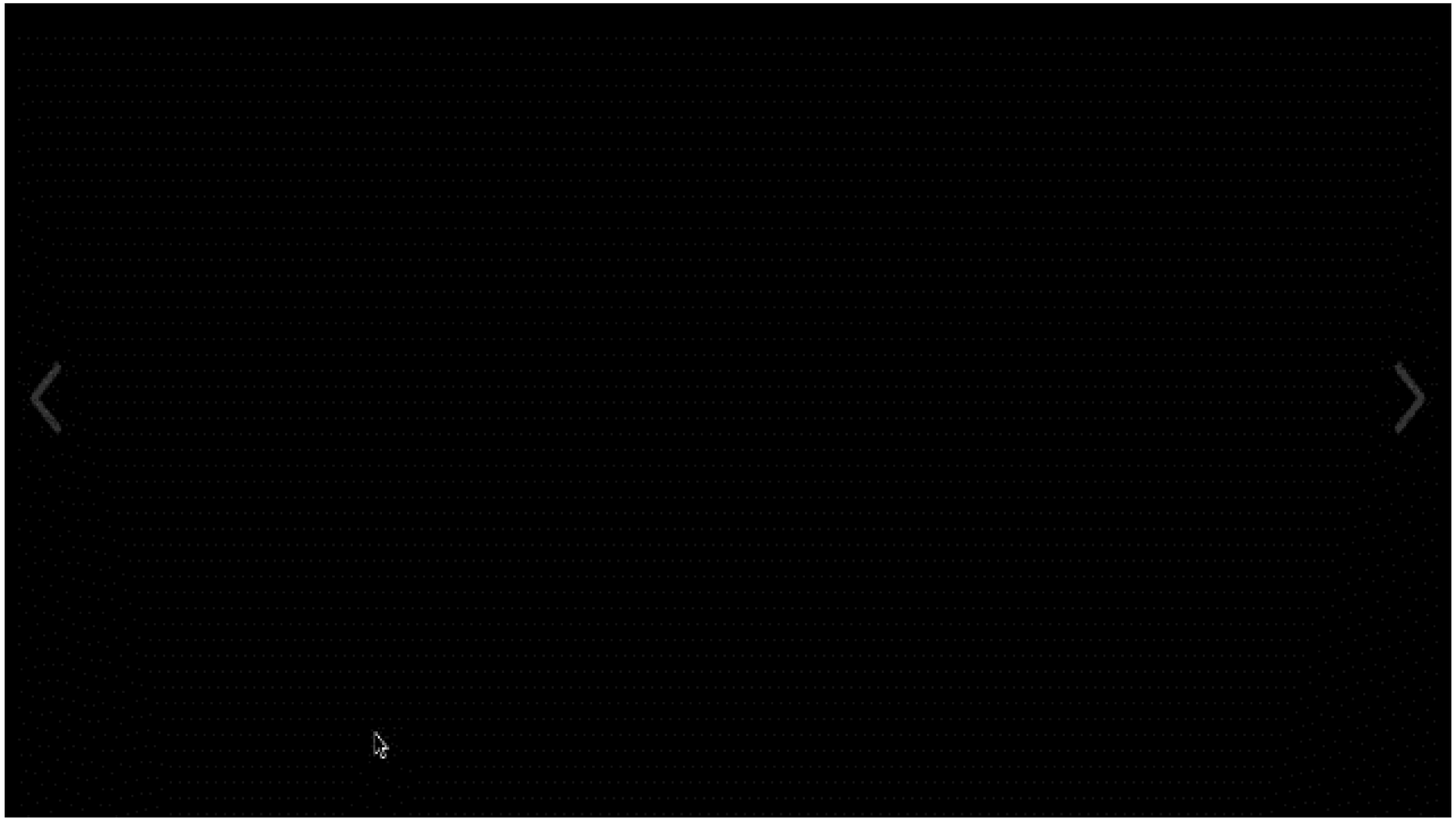
THE MONKEY BUSINESS ILLUSION



CINCINNATI ZOO GORILLA/TODDLER INCIDENT, MAY 28, 2016

CNN

Cincinnati gorilla incident: Police investigating boy's family

By Dominique Dodley, Sarah Jorgensen and Steve Visser CNN
Updated 3:14 PM ET, Thu June 2, 2016

Should we blame the mother for not paying enough attention to her child?

CINCINNATI ZOO GORILLA INCIDENT
MAY 28, 2016

Or should we make sure the next distracted mother doesn't have the same outcome?

LEARNING OBJECTIVES

1. Introduce key concepts concerning Human and Organizational Performance

    Create a paradigm shift in thinking about Safety

2. Demonstrate how HOP Theory has influenced EHS programs at Allergan

    R2P

Safety in the 21st Century
Human Performance Influenced EHS Programs

Good Observation Program

GM Weekly Safety Walk-Throughs

CAPA Council

Critical Safety Rules

Pre/Post-shift Musters and Critical Task(s) of the Day

EHS Alerts and Communication

Risk Maps

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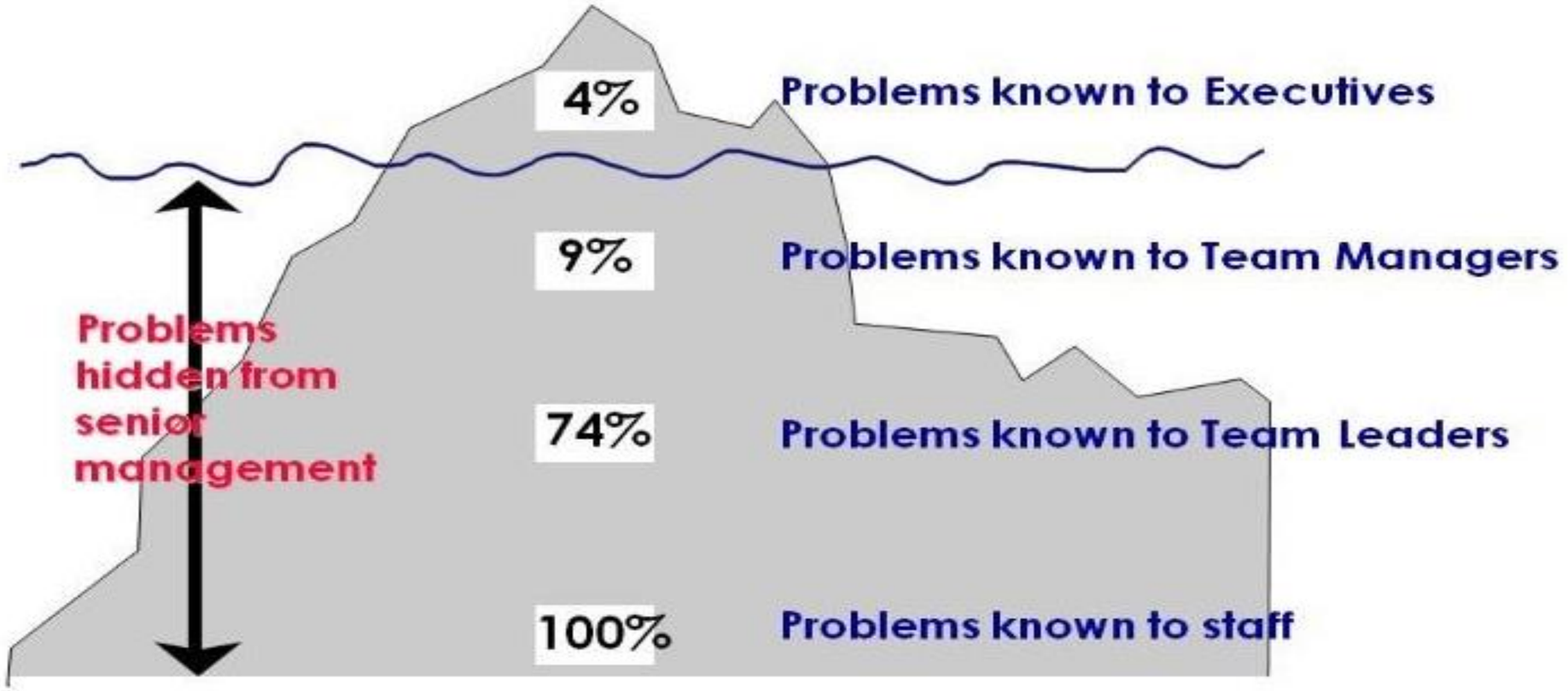
THE ICEBERG OF IGNORANCE



Adapted from
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Sydney Yoshida

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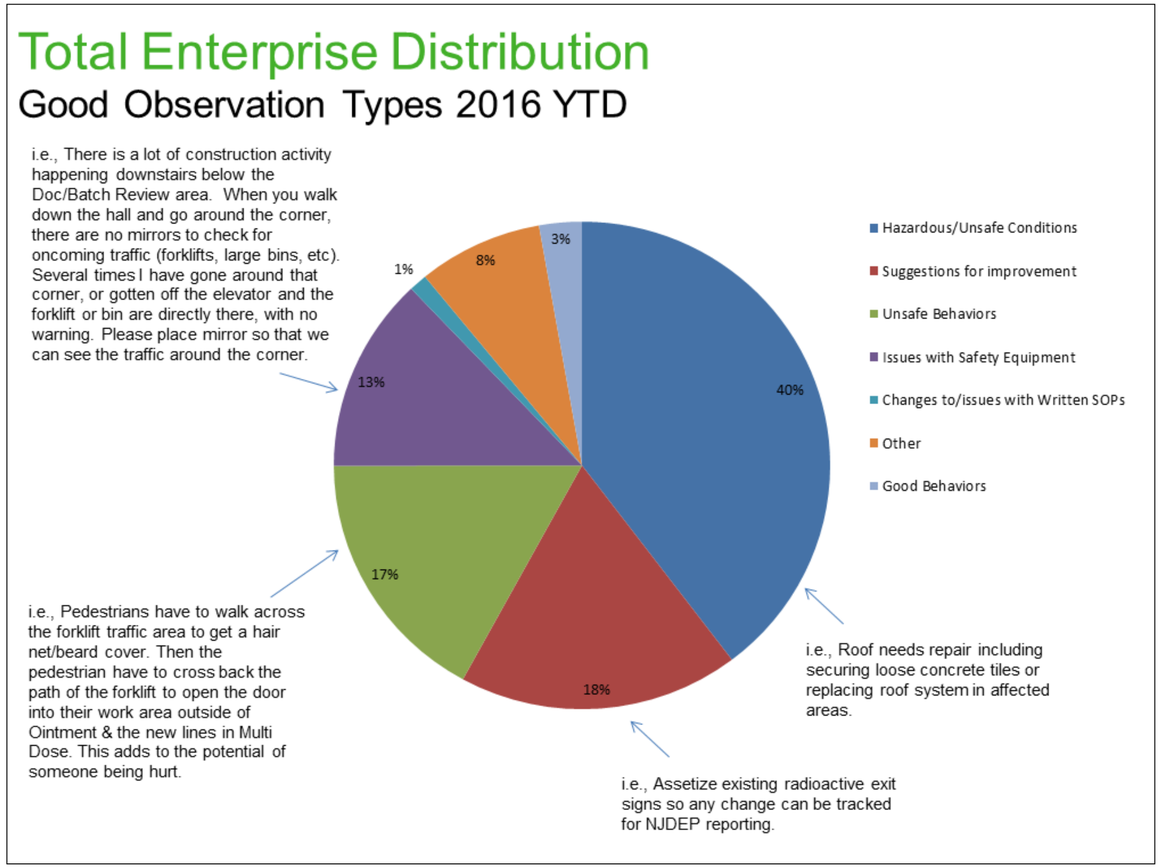
WHAT ARE GOOD OBSERVATIONS?

Goals

- Provide a mechanism for employees to provide management their knowledge
- Find and fix things before incidents occur
- Continually focus on risk reduction



Definition

- Documented employee observations that help prevent accidents from occurring. (EHS or management observations are excluded). Good observations may include near misses, unsafe acts or conditions and risk reduction suggestions.

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WHY GOOD OBSERVATIONS MATTER

The difference between a safe and unsafe organization lies not in how many incidents it has,

but in how it deals with the incidents that it has people report.

Sidney Dekker

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GOOD OBSERVATIONS

Started as a metric

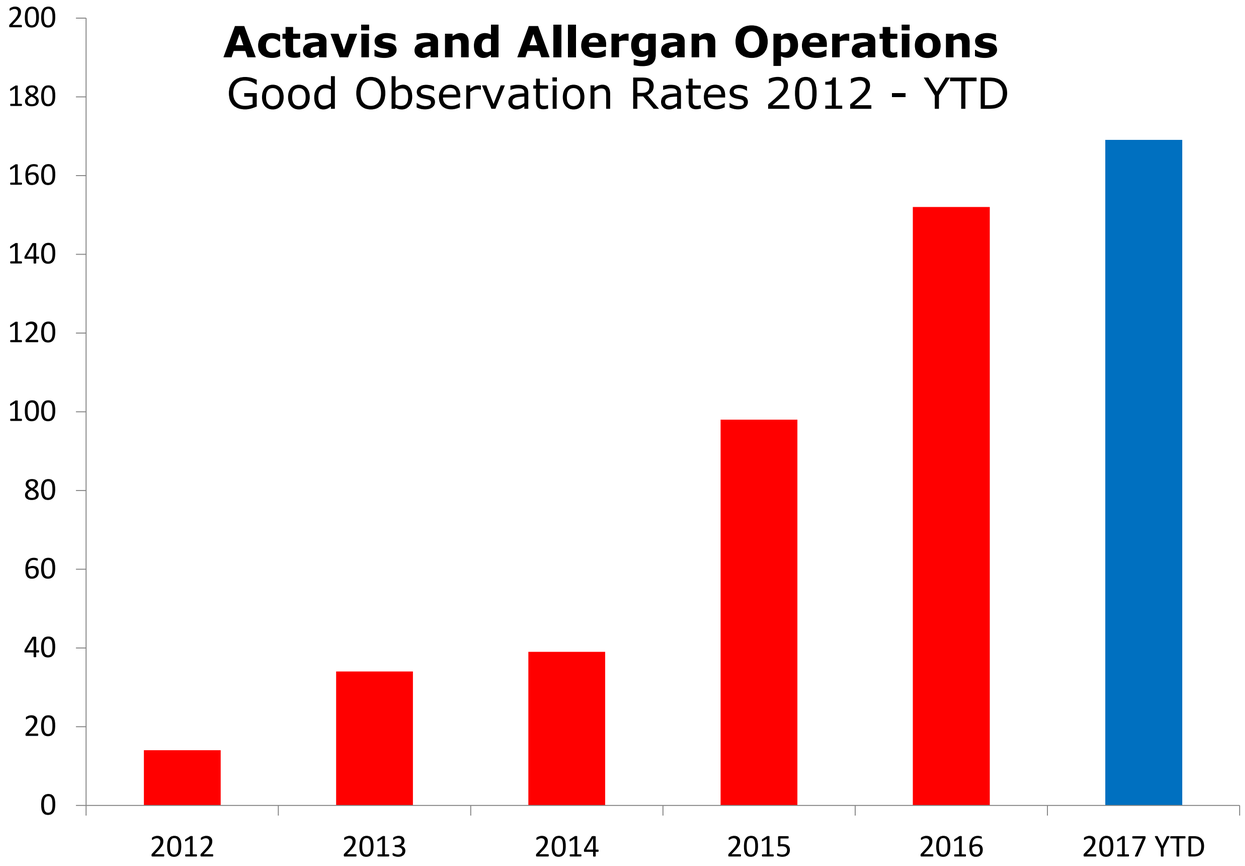
Value recognized quickly

Learning Culture

Sets expectations

Facilitates Positive Incentive Program

Becoming an expectation



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Leadership matters…

"The day soldiers stop bringing you their problems is the day you have stopped leading them. They have either lost confidence that you can help or concluded you do not care.

Either case is a failure of leadership."

Colin Powell

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HYPOTHESIS: GOOD OBSERVATION RATES ARE CORRELATED WITH INJURY RATE REDUCTION

DATA FOR SIGNIFICANCE TESTING

Sites	TRIR Counts 2014	TRIR 2014	TRIR 2015	TRIR Counts 2015	Rate Change	Good / Bad Injury Program	Good Observation Rate 2014	Good Observation Rate 2015	GO Rate Change 2014-2015	Good / Bad GO Program	Good Injury Good GO	Bad Injury Bad GO	Good Injury Bad GO	Bad Injury Good GO
	0	0.00	0	0	0.00	1	26	40	15	1	1	0	0	0
	5	5.30	1.16	1	-4.14	1	1	117	116	1	1	0	0	0
	6	0.99	0.48	3	-0.51	1	43	83	41	1	1	0	0	0
	0	0.00	4.01	2	4.01	0	12	22	10	0	0	1	0	0
	0	0.00	3.05	1	3.05	1	2	1	-1	0	0	0	1	0
	2	1.48	2.75	5	1.27	0	1	52	51	1	0	0	0	1
	12	4.42	0.68	2	-3.74	1	1	121	120	1	1	0	0	0
	0	0.00	0	0	0.00	1	345	347	2	1	1	0	0	0
	4	5.16	1.31	1	-3.85	1	203	466	264	1	1	0	0	0
	10	1.78	2.18	5	0.40	0	54	34	-21	0	0	1	0	0
	4	0.56	0.4	3	-0.16	1	1	12	11	0	0	0	1	0
	0	0.00	0	0	0.00	1	25	29	3	0	0	0	1	0
	11	1.86	2.92	18	1.06	0	69	79	10	1	0	0	0	1
	5	1.21	2.7	11	1.49	0	22	51	29	1	0	0	0	1
	0	0.00	0	0	0.00	1	1	37	36	1	1	0	0	0
	9	1.09	1.17	13	0.08	1	36	126	90	1	1	0	0	0
	0	0.00	0.33	3	0.33	0	36	51	15	1	0	0	0	1
	2	0.88	0	0	-0.88	1	29	52	24	1	1	0	0	0
	0	0.00	1.06	3	1.06	0	1	67	66	1	0	0	0	1
	4	1.72	2.02	4	0.30	0	30	42	12	1	0	0	0	1
	0	0.00	0	0	0.00	1	1	43	42	1	1	0	0	0
	4	1.16	1.2	4	0.04	1	85	138	53	1	1	0	0	0
	11	0.48	0.96	17	0.48	0	0	0	0	0	0	1	0	0
	0	0.00	0	0	0.00	1	51	57	6	1	1	0	0	0
	1	0.70	0	0	-0.70	1	124	230	106	1	1	0	0	0
	0	0.00	2.5	1	2.50	1	84	133	49	1	1	0	0	0
	1	1.00	0	0	-1.00	1	21	53	32	1	1	0	0	0
	4	1.01	2.11	9	1.10	0	60	49	-11	0	0	1	0	0
	4	2.07	2.06	4	-0.01	1	1	63	62	1	1	0	0	0
	0	0.00	2.26	3	2.26	0	189	147	-42	0	0	1	0	0
	0	0.00	0	0	0.00	1	53	64	11	1	1	0	0	0
	6	1.18	1	5	-0.18	1	34	71	37	1	1	0	0	0
	1	0.29	0.23	1	-0.06	1	39	45	7	1	1	0	0	0
	6	3.51	1.75	3	-1.76	1	27	39	12	1	1	0	0	0
	3	2.19	0	0	-2.19	1	1	43	42	1	1	0	0	0
	1	0.32	0	0	-0.32	1	71	95	24	1	1	0	0	0
	3	0.37	0.37	3	0.00	1	1	10	9	0	0	0	1	0
	1	0.38	1.25	3	0.87	0	7	8	1	0	0	1	0	0
	6	0.62	0.55	6	-0.07	1	1	269	268	1	1	0	0	0
	5	0.94	0.89	5	-0.05	1	52	57	5	1	1	0	0	0
40 Sites											Good Injury Good GO	Bad Injury Bad GO	Good Injury Bad GO	Bad Injury Good GO
										Subtotal	24	6	4	6

Good Observation Rate Thershold	35
Incident Count Theshold	1
Good Observation Rate Change Threshold	0
TRIR Change Threshold	0.1
Sites with Good Injury Status	28
Sites with Bad Injury Status	12
Sites with Good GO Program	30
Sites with Bad GO Program	10

We are scientifically certain (greater than 95% confident) that this relationship between Good Observation Rates and TRIR is not due to chance.

28 sites improved or stayed the same in 2015 vs 2014,
12 sites experienced rate increases.

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YATES CORRECTED CHI SQUARE TEST WITH A 2X2 CONTINGENCY TABLE

$$T = \frac{n\left(|ad-bc| - n/2\right)^2}{[(a+b)(c+d)(a+c)(b+d)]}$$

$$T = \frac{40\left(|144-24| - 40/2\right)^2}{[(30)(10)(28)(12)]} = 3.97$$

	Good Injury Rate	Poor Injury rate
Good GO Program	24 (a)	6 (b)
Poor GO Program	4 (c)	6 (d)

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Table 6 *Percentage points of the chi-square distribution* ($\chi^2_{d,p}$) §

	p													
d	*0.005*	*0.01*	*0.025*	*0.05*	*0.10*	*0.25*	*0.50*	*0.75*	*0.90*	*0.95*	*0.975*	*0.99*	*0.995*	*0.999*
1	0.0^4393*	0.0^3157†	0.0^3982‡	0.00393	0.02	0.10	0.45	1.32	2.71	3.84	5.02	6.63	7.88	10.83
2	0.0100	0.0201	0.0506	0.103	0.21	0.58	1.39	2.77	4.61	5.99	7.38	9.21	10.60	13.81
3	0.0717	0.115	0.216	0.352	0.58	1.21	2.37	4.11	6.25	7.81	9.35	11.34	12.84	16.27
4	0.207	0.297	0.484	0.711	1.06	1.92	3.36	5.39	7.78	9.49	11.14	13.28	14.86	18.47
5	0.412	0.554	0.831	1.15	1.61	2.67	4.35	6.63	9.24	11.07	12.83	15.09	16.75	20.52
6	0.676	0.872	1.24	1.64	2.20	3.45	5.35	7.84	10.64	12.59	14.45	16.81	18.55	22.46
7	0.989	1.24	1.69	2.17	2.83	4.25	6.35	9.04	12.02	14.07	16.01	18.48	20.28	24.32
8	1.34	1.65	2.18	2.73	3.49	5.07	7.34	10.22	13.36	15.51	17.53	20.09	21.95	26.12
9	1.73	2.09	2.70	3.33	4.17	5.90	8.34	11.39	14.68	16.92	19.02	21.67	23.59	27.88
10	2.16	2.56	3.25	3.94	4.87	6.74	9.34	12.55	15.99	18.31	20.48	23.21	25.19	29.59
11	2.60	3.05	3.82	4.57	5.58	7.58	10.34	13.70	17.28	19.68	21.92	24.72	26.76	31.26
12	3.07	3.57	4.40	5.23	6.30	8.44	11.34	14.85	18.55	21.03	23.34	26.22	28.30	32.91
13	3.57	4.11	5.01	5.89	7.04	9.30	12.34	15.98	19.81	22.36	24.74	27.69	29.82	34.53
14	4.07	4.66	5.63	6.57	7.79	10.17	13.34	17.12	21.06	23.68	26.12	29.14	31.32	36.12
15	4.60	5.23	6.27	7.26	8.55	11.04	14.34	18.25	22.31	25.00	27.49	30.58	32.80	37.70
16	5.14	5.81	6.91	7.96	9.31	11.91	15.34	19.37	23.54	26.30	28.85	32.00	34.27	39.25
17	5.70	6.41	7.56	8.67	10.09	12.79	16.34	20.49	24.77	27.59	30.19	33.41	35.72	40.79
18	6.26	7.01	8.23	9.39	10.86	13.68	17.34	21.60	25.99	28.87	31.53	34.81	37.16	42.31

THEREFORE:

According to percentage points of the chi square distribution table (Table 6) published in Rosner's Fundamentals of Biostatistics 2nd Edition 1986,

We are scientifically certain (greater than 95% confident) that this relationship between Good Observation Rates and TRIR is not due to chance. In other words,

We are scientifically certain that strong Good Observation rates are associated with improving Total Recordable Injury Rates.

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We've proved Correlation

But

Is there Cause and effect?

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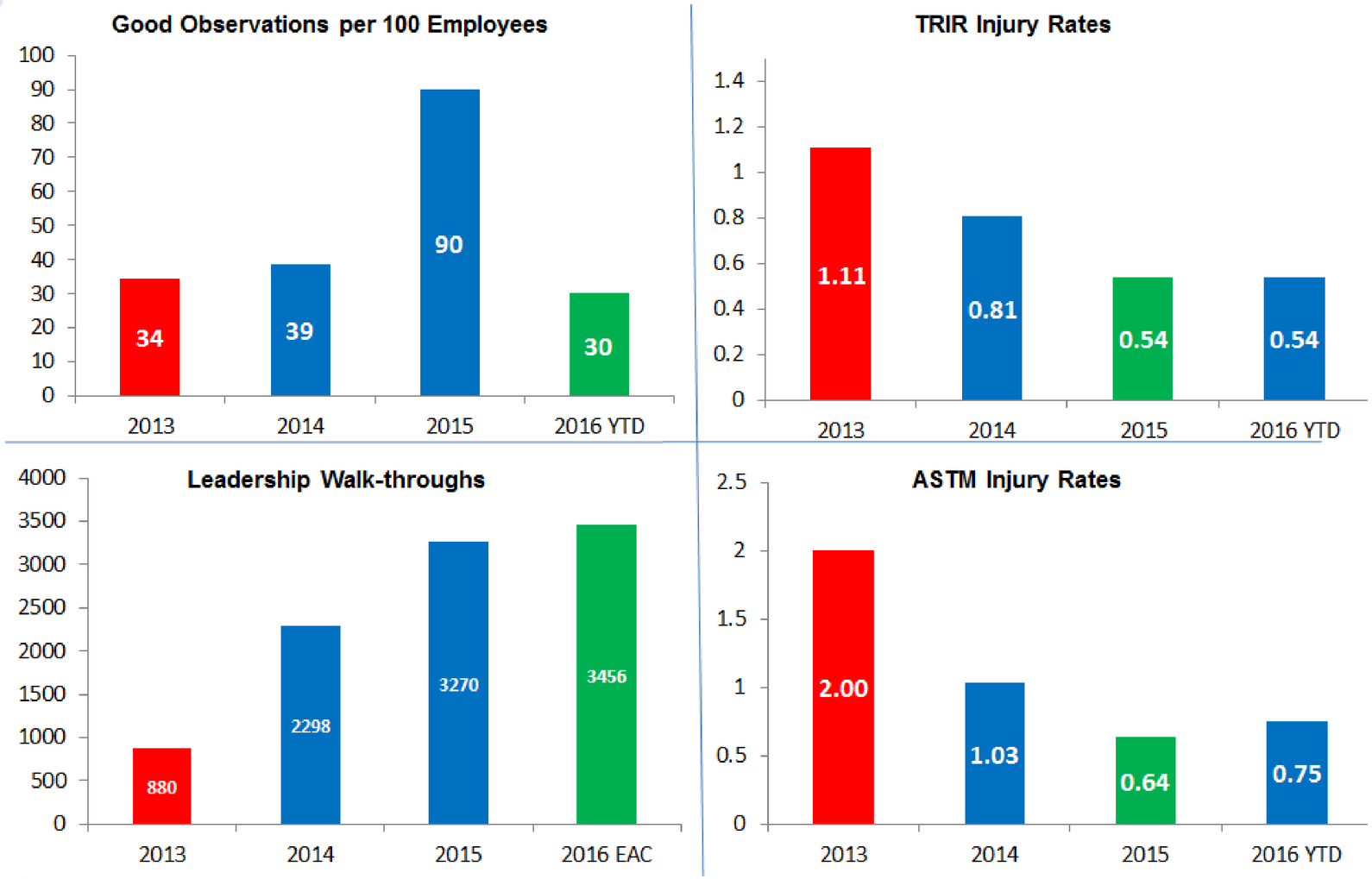
ENTERPRISE JAN 2016:
LEADERSHIP AND EMPLOYEE ENGAGEMENT
RELATIONSHIP TO INJURY RATES FREQUENCY AND SEVERITY



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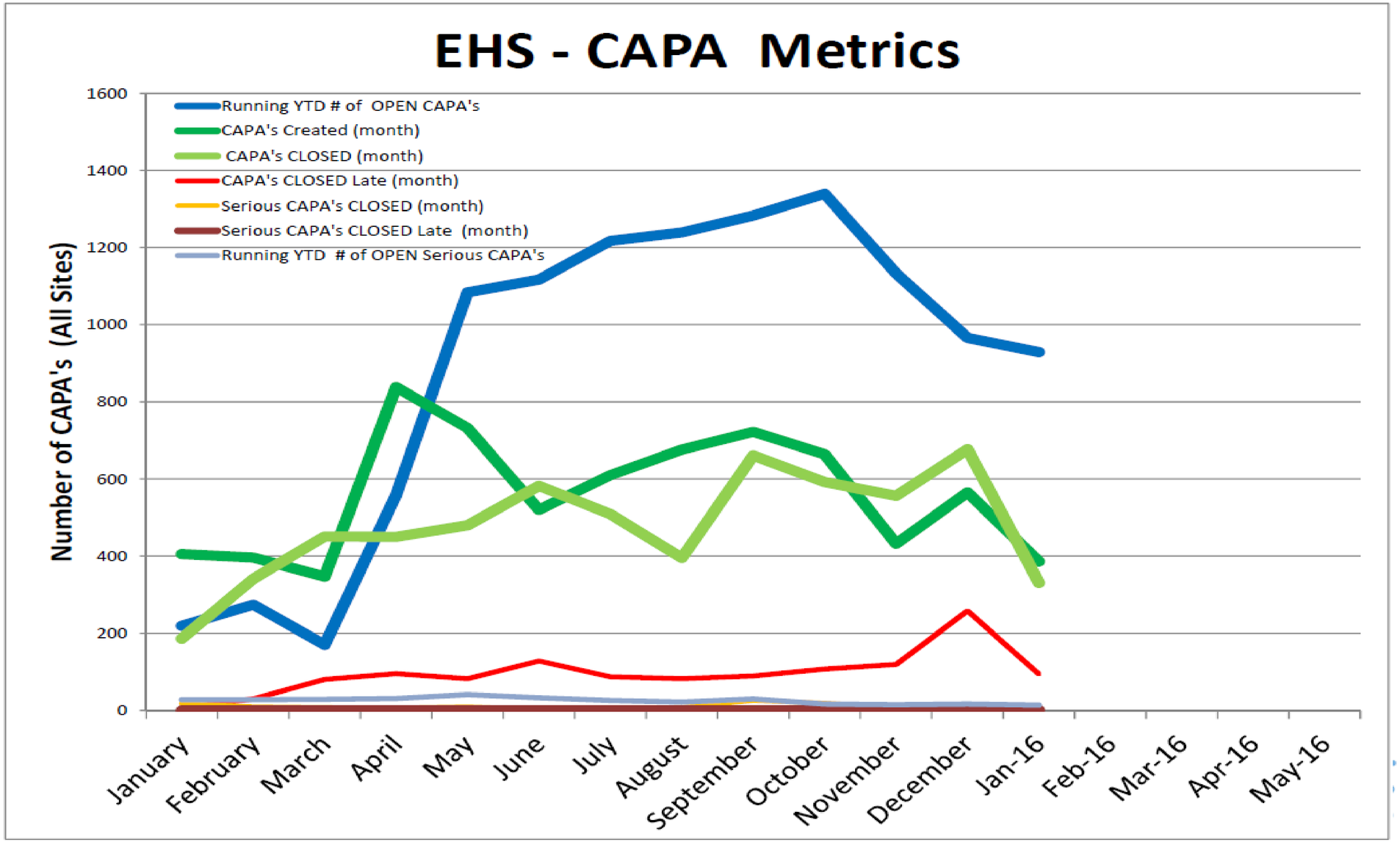
Overall Enterprise Performance January 2016



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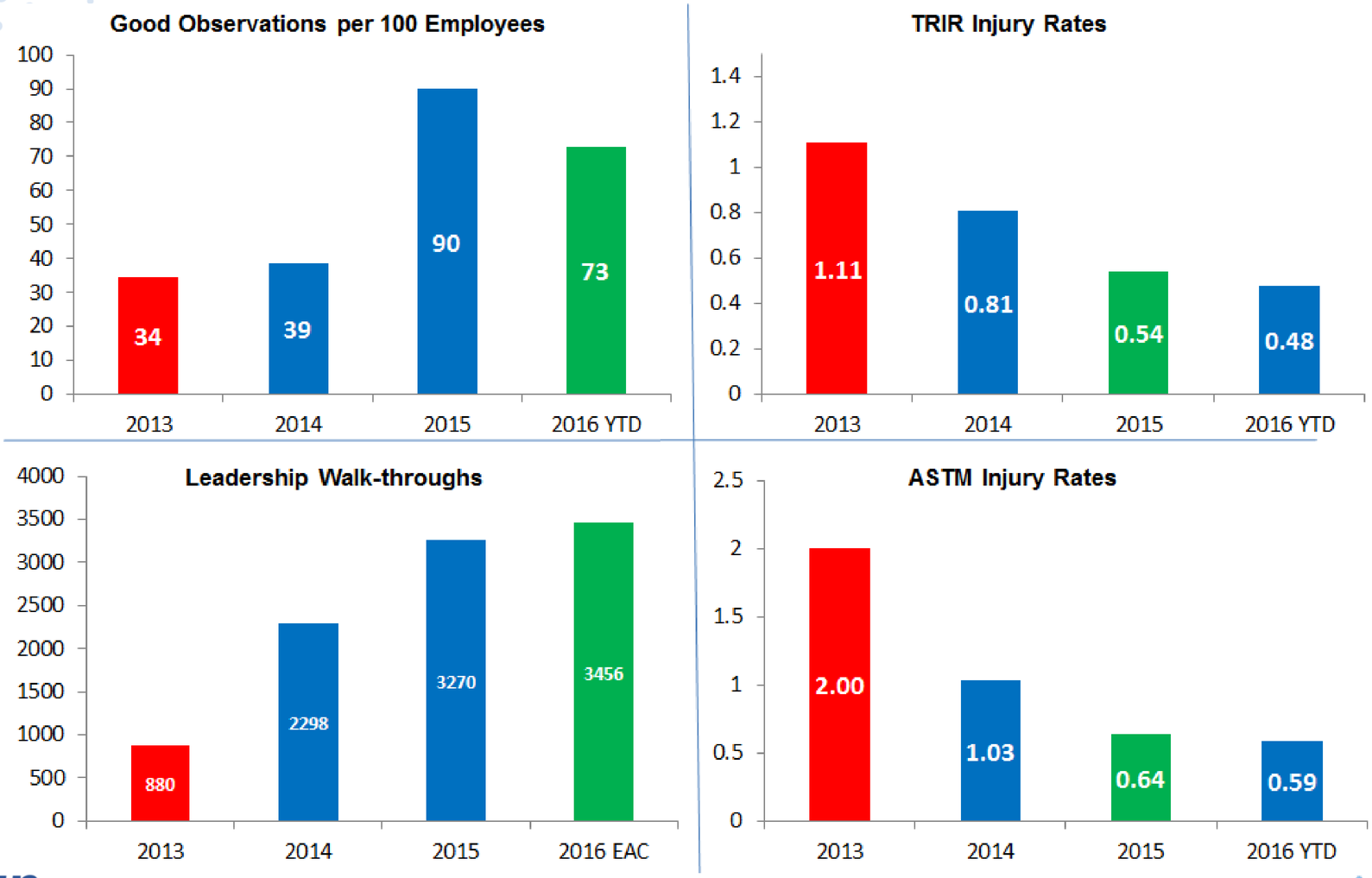
ENTERPRISE 2016 FEB YTD: LEADERSHIP AND EMPLOYEE ENGAGEMENT

RELATIONSHIP TO INJURY RATES FREQUENCY AND SEVERITY



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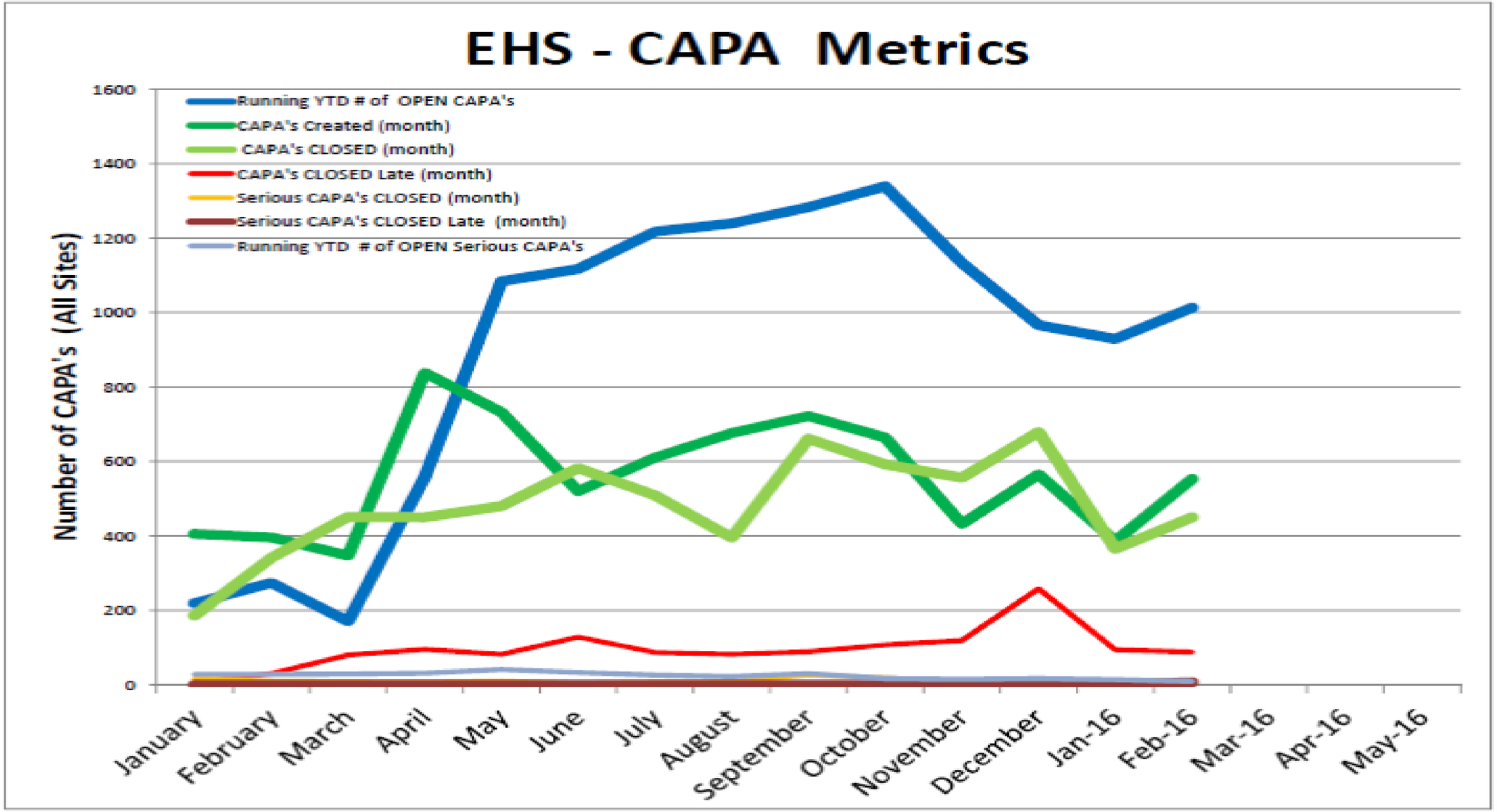
Overall Enterprise Performance February 2016



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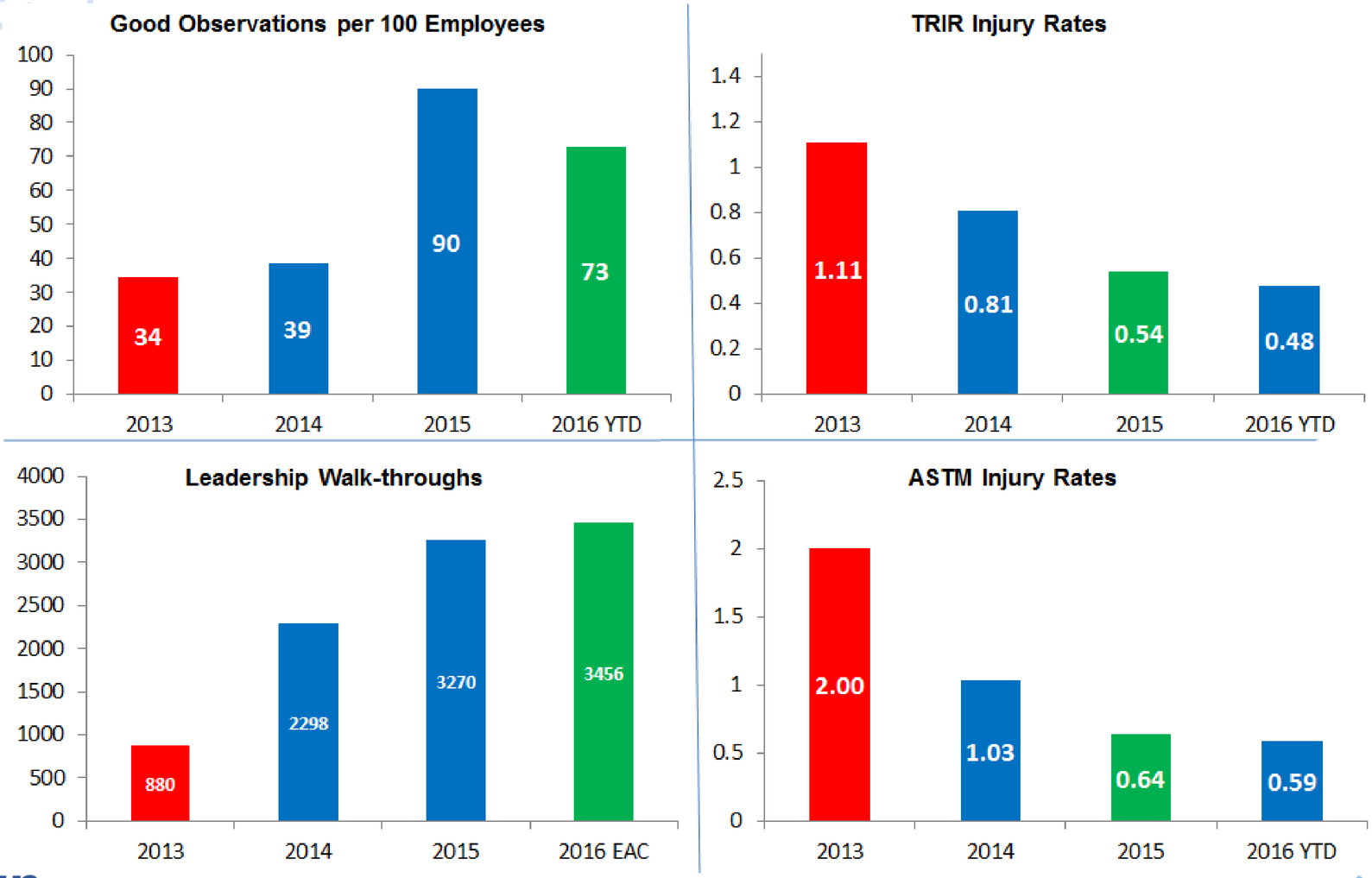
ENTERPRISE 2016 FEB YTD: LEADERSHIP AND EMPLOYEE ENGAGEMENT

RELATIONSHIP TO INJURY RATES FREQUENCY AND SEVERITY



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Coincidence?

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THE SEVEN DELUSIONS OF NEAR-ZERO ORGANIZATIONS

Corrie Pitzer, CEO SafeMap

Safety performance in many companies and even whole industries has stalled in the past few years. Accidents rates are at a “plateau” and yet, serious accidents and fatality rates are not. In more dramatic cases, such as in the BP Deepwater oil disaster, organizations that have “exemplary” safety statistics, suddenly have a catastrophic or multi-fatality event. Are there common features in these organizations’ mindset? What characterizes these organizations’ decision-making, their approach to safety and to risk and are there specific cultural features that can be delineated?

The reason your TRIR is so low is not simply because of employee engagement nor your high rate of CAPA closure (find-and-fix), but because you’ve convinced your employees to constantly look for hazards, unsafe conditions or actions to report per your Good Observation program. They’re simply more risk-aware and cognizant of their environment.

In other words, you’re coaxing them into a state of hyper-vigilance.

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GOOD OBSERVATIONS AND LEADERSHIP LEADING SAFETY

"…I want to thank you for participating in the "GO" program, your GO's are certainly worthy of winning but almost more importantly it is people like you that are driving this program forward and keeping the safety awareness high at our facility.

I believe that this program is the single biggest factor keeping people safe at the site.

If you think about it, if only the EHS team were actively involved in making the site safer, there is a real limit to how much they can get to observe and react to on a monthly basis. With the GO program, we have over 700 people having the ability to catch an issue before someone gets hurt.

Thank you again for your great GO's and helping keep all of us safe."

Dermot Manton – VP, GM Waco - 2017

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Safety in the 21st Century
Human Performance Influenced EHS Programs

Good Observation Program

GM Weekly Safety Walk-Throughs

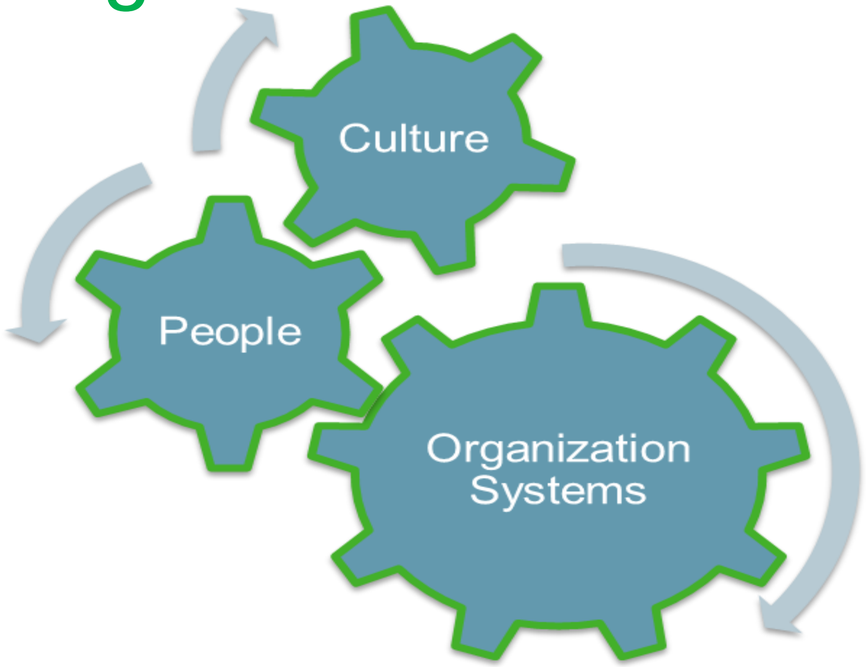
CAPA Council

Critical Safety Rules

Pre/Post-shift Musters and Critical Task(s) of the Day

EHS Alerts and Communication

Risk Maps



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CRITICAL SAFETY RULES
PRE-SHIFT MUSTERS

PURPOSE

2.1 Consider risk reduction measures that eliminate conditions that have a potential for a Serious Injury or Fatality (SIF) i.e., tasks that involve a Critical Safety Rule.

2.2 Prevent potential SIFs by conducting pre-shift risk assessments which address the two precursors of almost every fatal accident:

(1) There is sufficient energy in the process to kill

(2) The worker is often unaware of the critical risk i.e., they've become complacent.

Pre-shift risk assessments can prevent most, if not all, workplace fatalities by preventing complacency, ensuring the risks are well understood and that all precautions have been taken.

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THE FAST BRAIN AND THE SLOW BRAIN

Slow Brain – Analytical thoughtful actions

Fast Brain – “habitual/reactive/without thinking” Our actions are primarily directed by the fast brain

BRAIN-CENTERED HAZARDS: RISKS & REMEDIES

Susan L. Koen, Ph.D.

What if these brain-centered hazards are exacerbated by the fact that critical organizational elements—including work environments, technological interfaces, operating procedures, work schedules and even work cultures—**are not aligned with how the human brain actually works?**

Susan L. Koen, Ph.D.

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THREE QUESTIONS TO PREVENT SIF'S

1. What task could cause immediate, non-recoverable harm to people or the facility?
2. What should we do to ensure this task for this work at this time is successful?
3. When this task fails, what is it that keeps you from being killed or seriously injured? Is that enough?

Todd Conklin, Ph.D.

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PRE-SHIFT MUSTER DISCUSSIONS DEFEAT COMPLACENCY

Do any of our planned tasks today involve a critical safety rule?

Do any of these conditions exist?

Error Traps and Error-Likely Situations

- Rushing
- High workload
- Unclear labeling
- Inaccurate procedures
- Unexpected conditions
- Stress
- Unclear expectations
- Multi-tasking
- Interrupted work
- Work-arounds
- New technique
- 1st time performing task
- Double Shift / Fatigue

Agree on Stop Work Criteria.

Discuss precise criteria before shift begins

Write them down and agree upon them

This in addition to Critical Tasks of the Day

Discuss the Critical Control

Consult the Supervisor prior to initiating the task

Tools available to facilitate this process

SPEAK – Pre-shift and CLEAR – Post Shift

Start When Sure

PRE-SHIFT MUSTER EXAMPLE

ARE WE HANDLING ANY FLAMMABLE SOLVENTS OR REACTIVE CHEMICALS TODAY IN ANY OF OUR PROCESS STEPS?

WHAT CONTROLS ARE IN PLACE TO PREVENT A FIRE, AN EXOTHERMIC RXN OR EXPLOSION?

Stop Work Criteria?

DO WE HAVE TO WORK ANYWHERE TODAY ABOVE SIX FEET FROM THE GROUND?

ARE THERE RAILINGS IN PLACE?

DO YOU HAVE TO CARRY ANYTHING UP OR DOWN?

WHAT PRECAUTIONS WILL YOU TAKE?

COME GET ME BEFORE YOU DO THIS. OKAY?

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IN CONCLUSION

The difference between a safe and unsafe organization lies not in how many incidents it has,

but in how it deals with the incidents that it has people report.

Sidney Dekker

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Thank you for your valuable time!

Questions?