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A Fresh Approach to Risk Assessment & FMEA

It's all about severity

Beverly Daniels

FEBRUARY 25, 2020

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IDEXX Designs and manufactures diagnostic tests and support services for Veterinary practices, Dairy Processors and Water Treatment plants.
IDEXX has a complex and diverse Customer base as well as a strong portfolio of products that rely on a complex mixture of engineering and scientific disciplines.
IDEXX has manufacturing, service and distribution centers across the world to support a global market.
When IDEXX began its Lean and Six Sigma journey in 2004 it was a $650M company, today, twelve years later it is a $1.8B company. This growth has provided a fertile and culturally diverse environment in which to develop and refine the approaches for a successful Lean and Six Sigma program.


Contents
The Case Against the RPN
A Logical Approach to Assessing Risk
Risk Assessment for Active Excursions and Business Risk
Supplemental Material and References
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Learning Outcomes

- Understand why RPN values are flawed resulting in incorrect conclusions.
- Understand why likelihood is impossible and irrelevant to assess.
- Accurately assess product changes that might affect quality.

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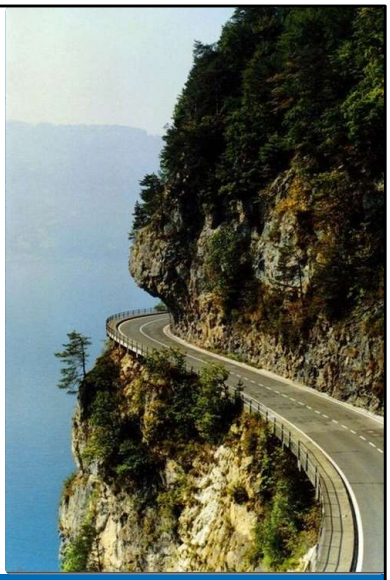
What is Risk?

What does risk mean to *you?*



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The Amalfi coast. Pinterest.

What is Risk?

What is a reasonable risk?

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The key here is that the person taking the 'risk' won't be affected by the adverse consequences.
They won't pay for the overtime, take the angry phone calls, buy more raw materials to make replacement parts, perform the service, provide the free goods,…

Image: https://i.dailymail.co.uk/i/pix/2013/03/24/article-2298443-18E4339A000005DC-516_634x430.jpg from article "**So, this is how adrenaline junkies relax! Fearless daredevil takes a break and LIES DOWN on wire 3,000ft above the Rio skyline" Daily Mail March 24, 2013**
https://www.dailymail.co.uk/news/article-2298443/So-adrenaline-junkies-relax-Fearless-daredevil-takes-break-LIES-DOWN-wire-3-000ft-Rio-skyline.html

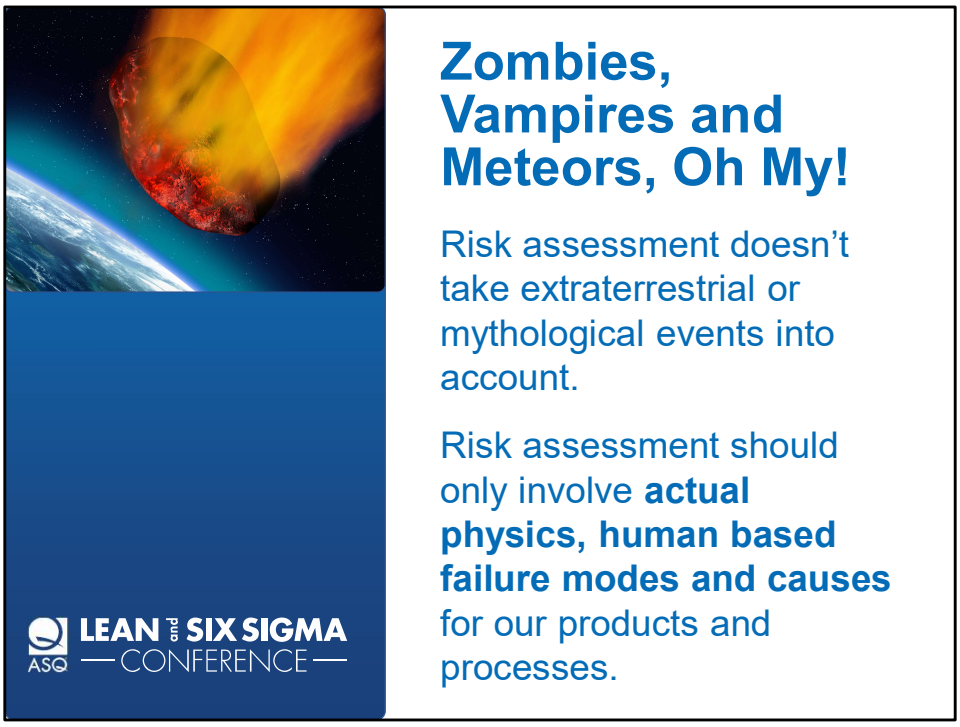
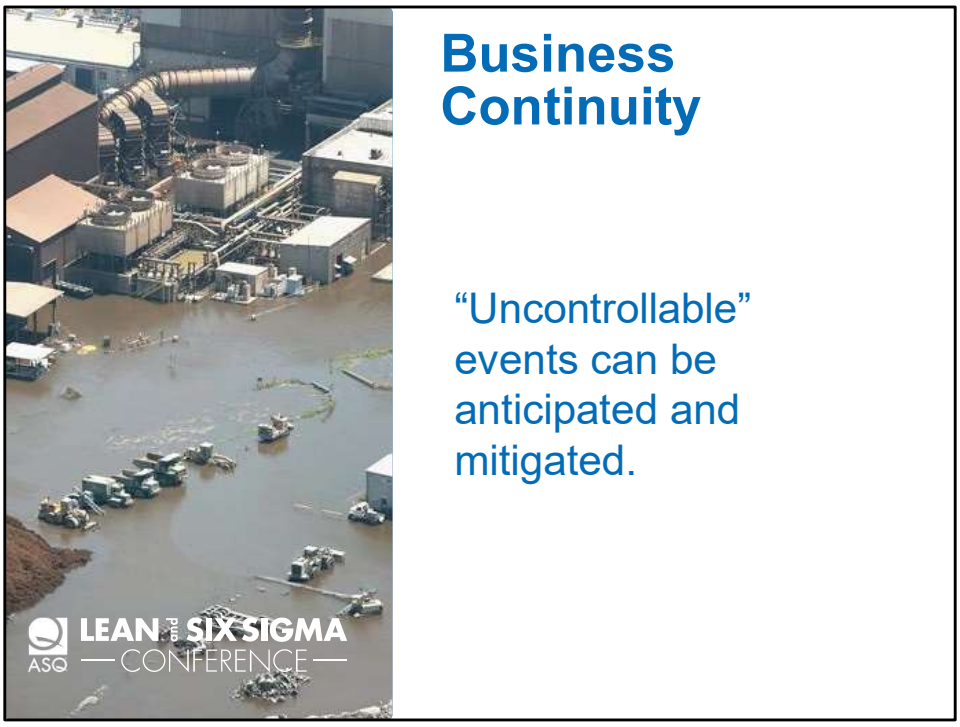


Image: ID 29046436 © Paul Fleet Dreamstime.com



Houston flooding in 2017 took petrochemical suppliers off line until 2018. Resins were constrained world wide. Both the manufacturing capacity and the logistics of material delivery, employee access and shipping were effected.
It was the 3rd 500 year flood in three years…

Examples:

- Fire, explosions
- Snow & ice storms, tornadoes, hurricanes, droughts, plagues
- Supplier Bankruptcy
- Theft, corruption
- Sabotage, terrorism
- Labor strikes

Image: Source: © Scott Olson/Getty Images
From the article "Hurricane hammers US chemical industry" by Rebecca Trager published September 1, 2017 in ChemistryWorld, https://www.chemistryworld.com/news/hurricane-hammers-us-chemical-industry/3007929.article

A Common Definition of "Risk"

The **probability** and **magnitude** of an undesirable event.

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In other words, "Something bad could happen"…

Stock image, multiple sources

IDEXX "FMEA" Assessing Product Risk

Only Severity is considered:

- No RPN values
- No Occurrence or Detection ratings
- Single universal 1-5 Severity scale.

Prevention, control and mitigation is **required for all high severity (≥3) failures.**

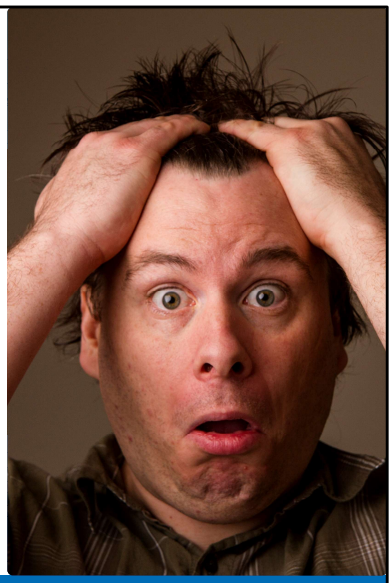

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Image: D 49117329 © Tracy King Dreamstime.com dreamstime_xxl_49117329.jpg

IDEXX uses this approach for design and process FMEAs during development. During an active excursion we will use the actual occurrence rate. It's not transformed into an ordinal ranking.

Always Protect the Customer

Effective risk assessment begins with **respect** and **empathy** for the Customer.

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Responsible risk management balances risk aversion and risk attraction

Responsible risk management is essential to continual improvement

Responsible risk management enables **bold innovation** and **continual improvement** while **minimizing adverse consequences**.

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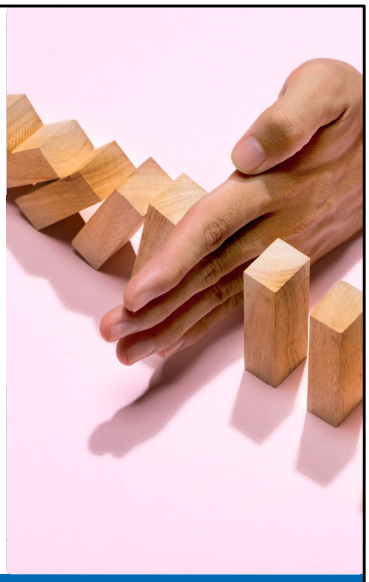
Purpose of Risk Assessments and V&V

Prevention of Problems

Detection of future Problems

Mitigation of failures and their effects



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When Risk Assessment is Performed

During **development.**

For any **change** that could potentially product affect form, fit or function.

When considering releasing a change without validation to **mitigate supply discontinuity.**

During an **active excursion** for prioritization.

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ID 23797962 © Leung Cho Pan Dreamstime.com

Risk Assessment During Post Launch Changes

Changes that could potentially affect **form, fit or function**:

- Material, process, QC testing, specification or product changes.
- Supplier changes, manufacturing moves, equipment maintenance.

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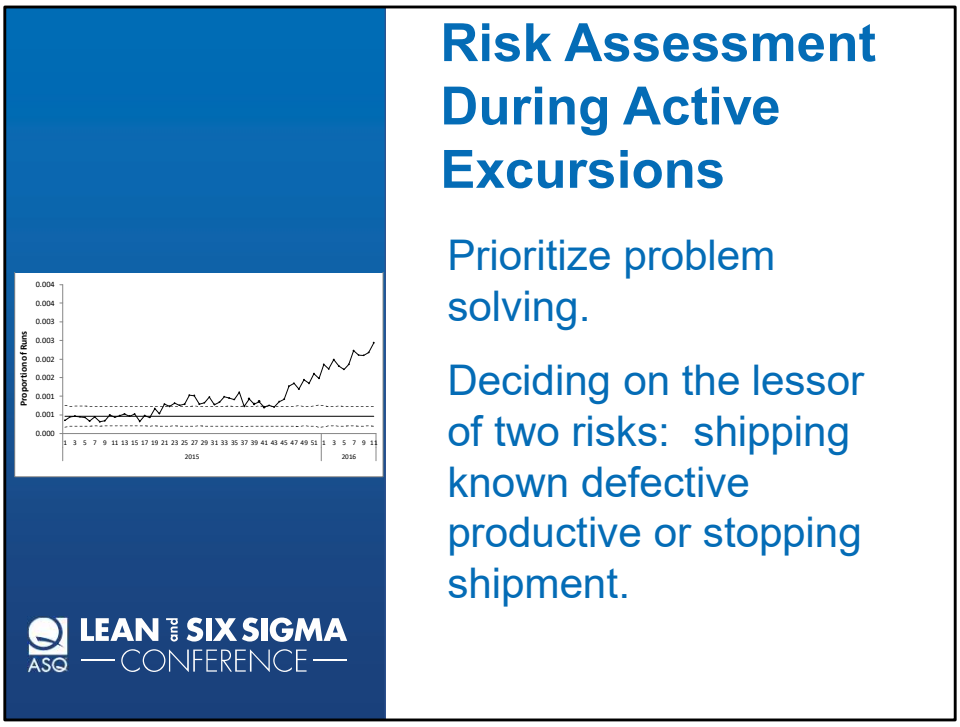
Internal IDEXX photo Joe Rotford photographer



Stock image, multiple sources

The Case Against the RPN and S*O

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Ordinal Ranking

Severity, Occurrence and Detection are given a **rank score** from 1-5 or 1-10

Severity:	1 = lowest severity
	5 = highest severity
Occurrence:	1 = lowest probability/defect rate
	5 = highest probability/defect rate
Detection:	1 = Certain detection
	5 = Detection Impossible

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Ordinal Data Cannot be Multiplied

The mathematical requirements for a multiplied number to have meaning:

1. The values must have **sequence**
2. The values must have **equal width**
3. The values must be **equidistant** from each other
4. The scale must have an absolute zero

This is the definition of ratio data

Ranking Scales Violate the Rules of Mathematics

Rank	Occurrence Rate	
1	0.00000067	≤ 0.67 ppm
2	0.0000067	
3	0.000067	
4	0.0005	
5	0.0025	
6	0.0125	
7	0.050	
8	0.125	
9	0.33	
10	0.50	≥ 50%

Cell widths are not equal.

Distances between cells are not equal.

The scale has no absolute zero.

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Qualitative Assessment = Fuzzy Values

Occurrence is rarely measured.

Occurrence is subject to guessing, personal experience, opinion and biases.

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Image: stock photo

Cognitive Dissonance

The **scoring method is fundamentally flawed.**

The **resulting number has no reliable meaning.**

Yet, we **persist** in using it and **making decisions based on it.**

Because it's a number?

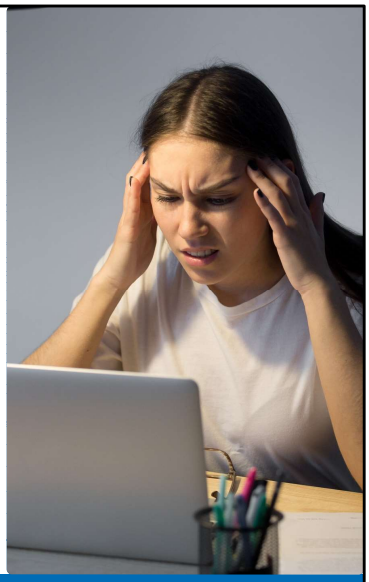

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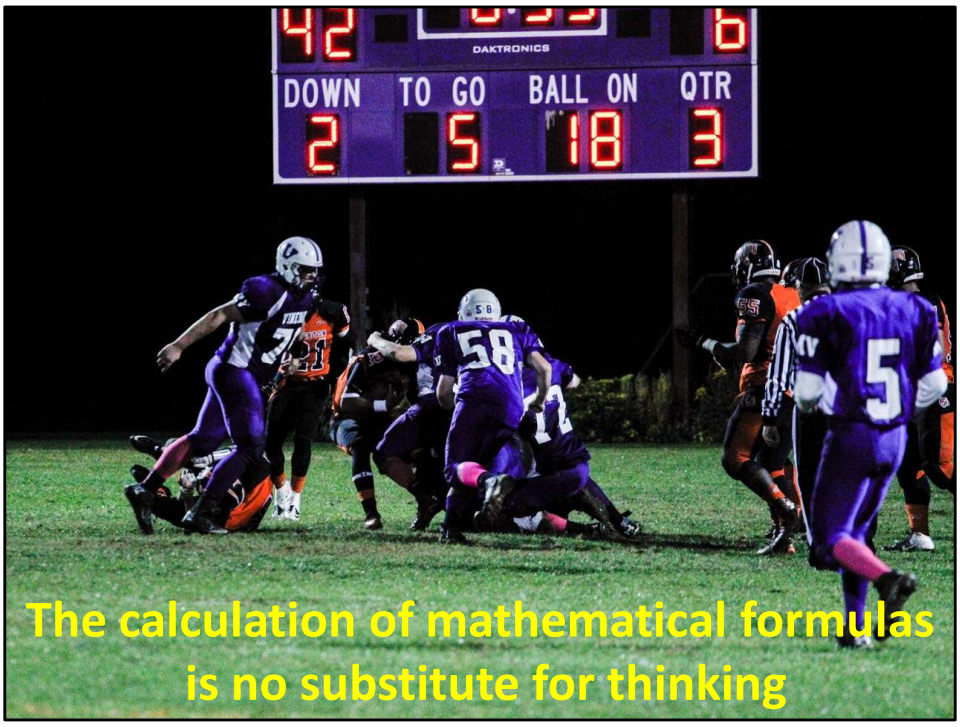
Image: ID 117077290 © Fizkes Dreamstime.com



A paraphrase of Herman Blalock (Social Statistics, 1972) who made a wonderful comment on the over use of statistical computations that succinctly summarizes this point: "the statistical manipulation of formulas is no substitute for knowing what one is doing".

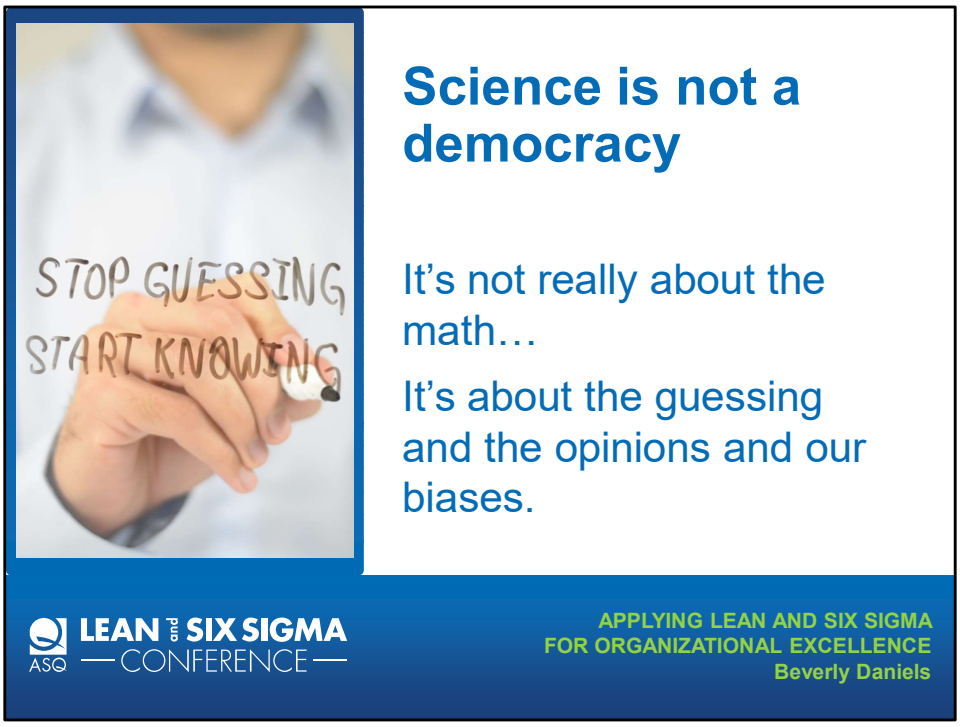


Image: ID 99203199 © Stockbakery Dreamstime.com

The Purpose of FMEA is to prevent and mitigate failures

Guessing at Occurrence is a waste of emotion, time and energy.

It is subject to gamesmanship which diverts attention from the intent of FMEA.

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How to use occurrence

Occurrence should only be **used to determine sample sizes** for characterization and V&V testing.

This occurrence is not a guess but a business requirement: **What is the maximum acceptable defect rate for the Customer?**

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Quantifying a priori Risk

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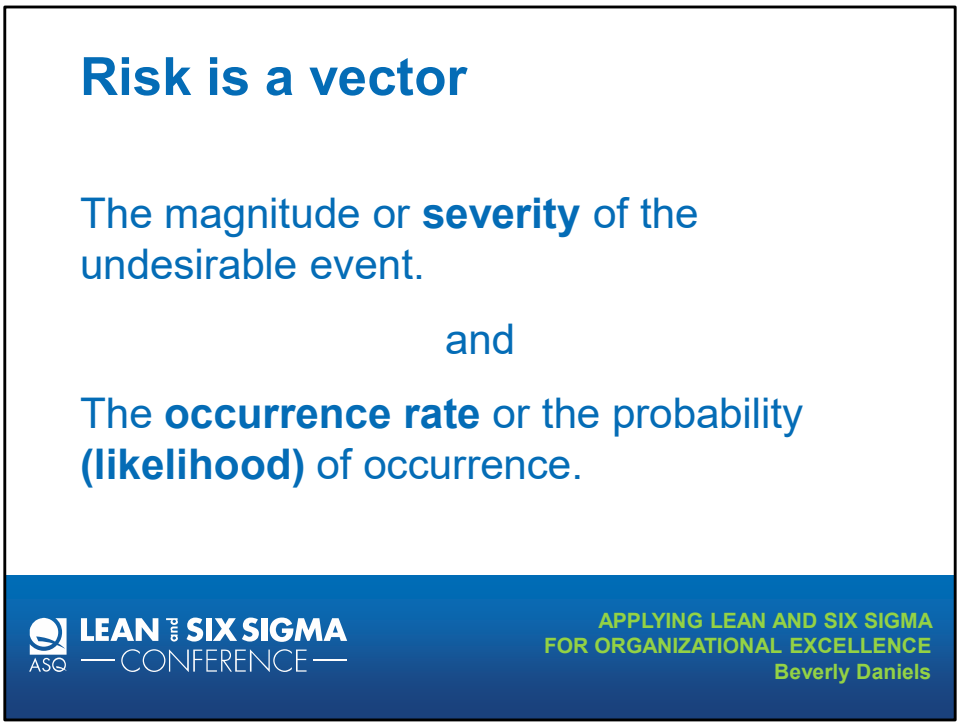

Detection is a mitigation to reduce the overall effect of occurrence of the event. Detection moves the occurrence of some – but not all – events upstream of the user. The effect of an in-house detection is less than the effect of one detected by or occurring to the Customer.

Severity of Effect

Severity is an input to risk assessment.

Severity can be logically determined thru our scientific and practical knowledge of the system.

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The Severity Rating Scale: Keep it Simple

Simple

Clearly defined categories

Used by everyone

Rank	Description
1	Negligible
2	Minor
3	Serious
4	Critical
5	Catastrophic

Severity level names and definitions based on ISO14971-2007 Table D3, section D.3.4.2, page 38

Occurrence

Occurrence is an output of risk assessment and mitigation.

An ineffective mitigation and/or control plan will result in a high defect rate when an excursion occurs.

An effective mitigation and control plan will prevent an excursion or detect it early and reduce the overall occurrence.

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Occurrence is Complicated

Occurrence rate or defect rate refers to the actual occurrence of defects given the total opportunity for a defect.

Probability or likelihood of occurrence refers to the relative 'probability' that defects will occur. The actual defect rate is unspecified.

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Occurrence Rate

The popular “occurrence ratings” tables use the occurrence or defect rate.

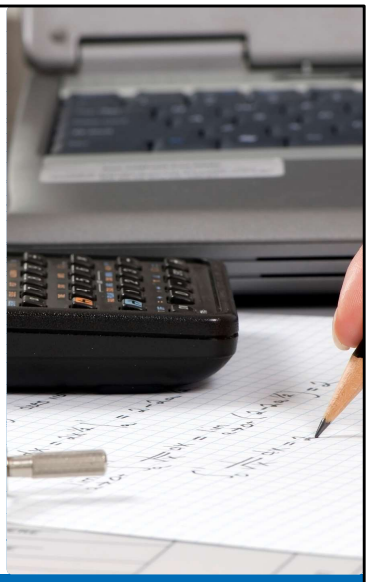

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Image: Photo 2216694 © Thomas Perkins - Dreamstime.com

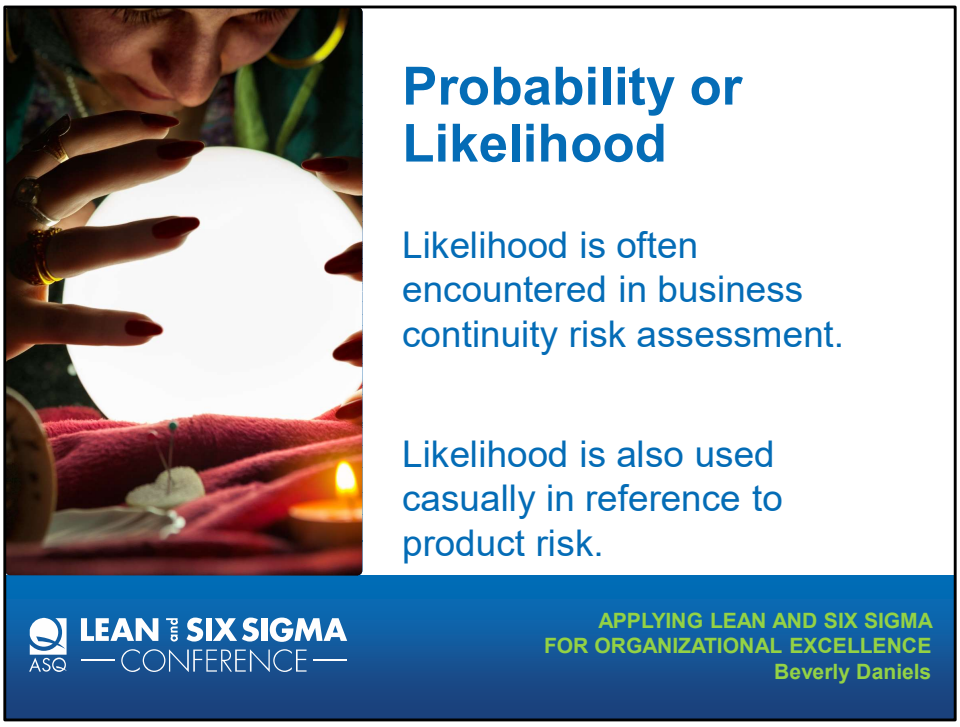

Image: Photo 87992743 © Cherriesjd - Dreamstime.com

Which Likelihood?

Is it the likelihood that the tolerances are wrong?

Is it the probability or likelihood of an excursion outside of the tolerances?

Is it the likelihood that an unknown factor will cause failure?

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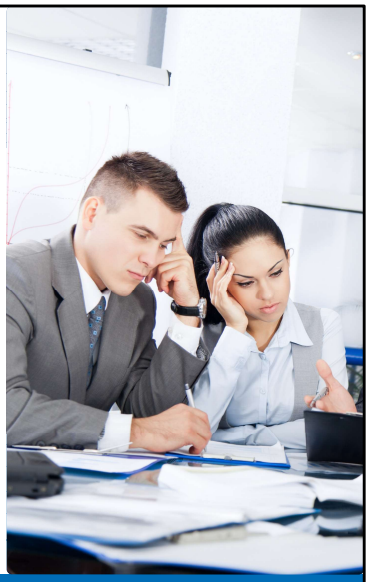
Image: © Mast3R ID 27976973 dreamstime.com

Which Defect Occurrence Rate?

Is it the defect rate of any given excursion? Which excursion?

Is it the defect rate of a factor that is out of specification?

Is it the defect (failure) rate the Customer experiences even when parts are “in tolerance”?



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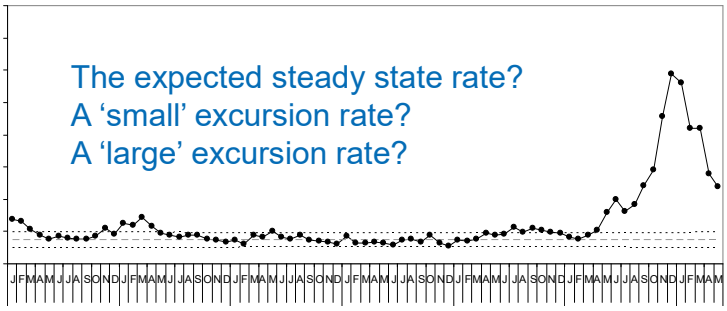
EXAMPLE

Which Occurrence Rate?



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This is the historical data of the trend of a specific defect (failure mode) for the past several years just prior to a material change…even with reliable, accurate historical data which occurrence rate should we have used?

How is Occurrence Determined?

- ✗ Historical data?
- ✗ Opinion?
- ✗ Crystal ball?
- ✓ **Actual Testing**

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Image: © Mast3R ID 27976995 Dreamstime.com

Determining *Expected* Occurrence Rates

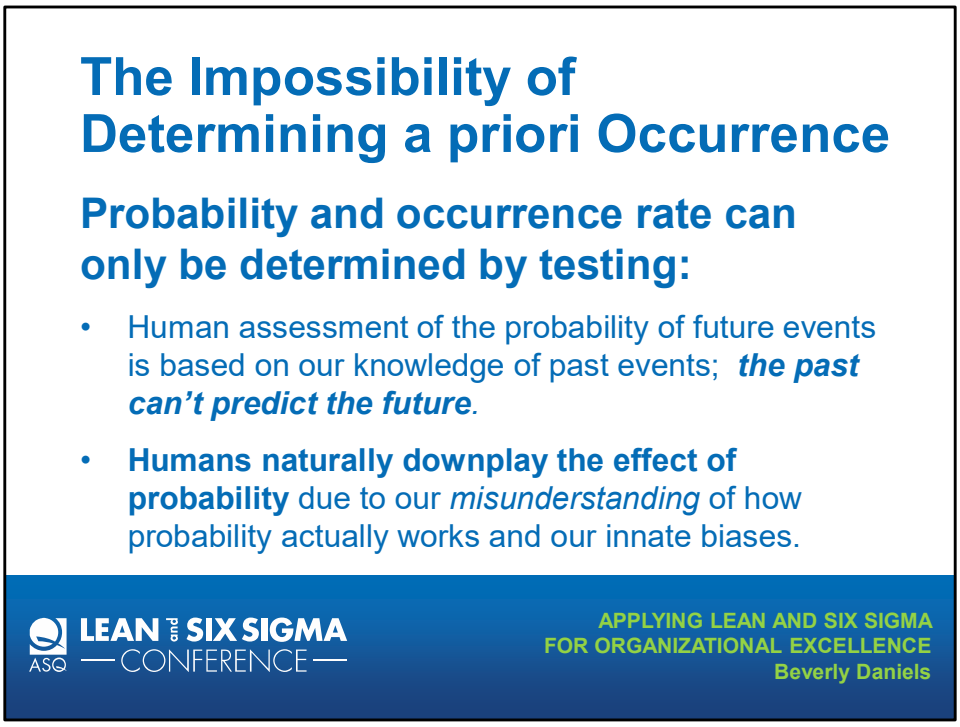
Characterization during design.

Validation testing at worst case conditions.

- During design
- When a material, process or design change is made

Capability studies.

This is only the expected occurrence rate at steady state conditions.



We may ask "what are the odds?" but we rarely calculate them even when it is possible, we choose instead to 'guess' and typically underestimate the odds.

Even when scientifically quantified it is too often misunderstood and minimized We often underestimate the number of occurrences for low probabilities because we fail to comprehend the true area of opportunity. For example, an event that has a 1 in a million chance of occurring will occur every day if there are a million opportunities per day

For every rule there is an important exception. During a period of time when a known defect is occurring, we can use statistics and probability to determine the occurrence rate in the Customer's hands. This is useful information in making business decisions about short term and long term containment and mitigation. But this frequency or probability is only valid for the specific event.

A small rate of occurrence with a large opportunity for occurrence is still a big number.

Further complicating things: Because causes aren't necessarily randomly – or

homogenously – distributed, a 5% rate doesn't' mean that 1 in every 5 things will have the defect. You might experience 5 in a row with the defect then, 25 or 30 without the defect…

Detection

Can only be determined by testing (MSA).

Occurrence and detection are **dependent** on each other.

Detection is really a mitigation that reduces the occurrence and downstream cost of a defect.

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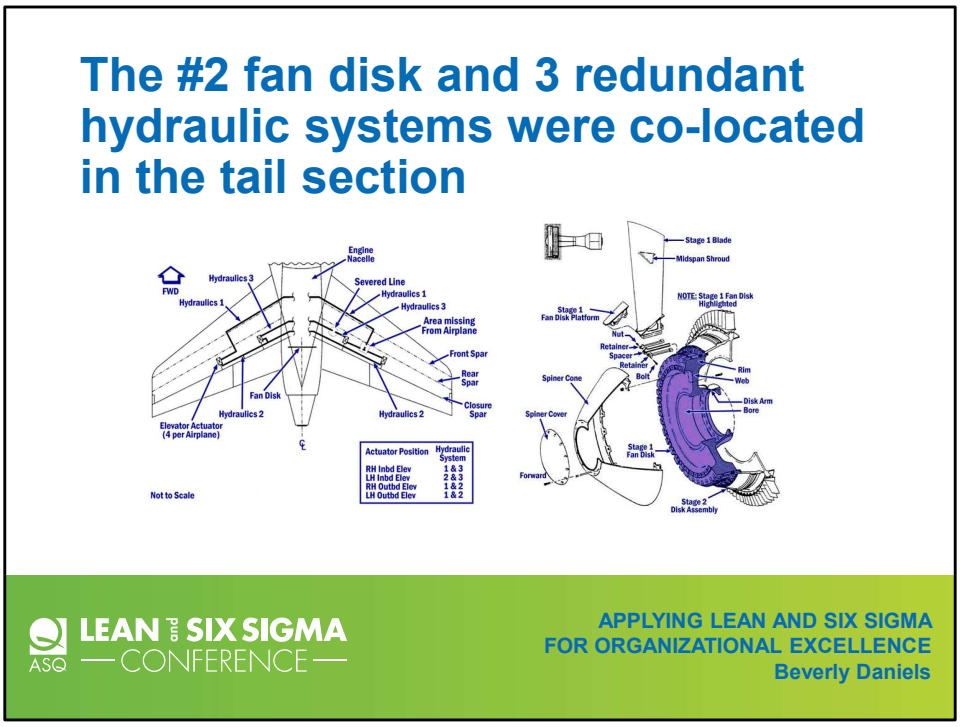
Image: Iowa Department of Public Safety

The co-location of the hydraulic systems is referred to as a “single point of failure” The loss of hydraulics resulting in using engine thrust variations in the two remaining wing mounted engines to steer and to descend. However the plane speed could not be lowered sufficiently and the plane could not ‘flare up’ upon landing. This resulted in a high impact without the ability to break, a crash landing.



Images: https://lessonslearned.faa.gov/ll_main.cfm?TabID=3&LLID=17

Hydraulic routing
https://lessonslearned.faa.gov/United232/United232_arrangement_pop_up.htm
Fan Disk, FAA Lessons Learned,
https://lessonslearned.faa.gov/United232/United232_fan_disk_pop_up.htm

Aircraft Accident Report, United Airlines Flight 232, McDonnell Douglas DC-10-10, Sioux Gateway Airport, Sioux City, Iowa, July 19, 1989, National Transportation Safety Board, November 1, 1990. NTSB/AAR-90/06.
https://www.ntsb.gov/investigations/AccidentReports/Reports/AAR-90-06.pdf
NTSB/AAR-90/06 PB90-9 I 0406

NASA System Failure Case Studies July 2008 Volume 2, Issue 6. No Left Turns
https://sma.nasa.gov/docs/default-source/safety-messages/safetymessage-2008-08-01-unitedairlinesflight232crash.pdf?sfvrsn=fba91ef8_4

The odds of total hydraulic failure were put at “1 in a billion”

Probability depends on exposure.

A billion what?

- Planes?
- Flights of a single plane?
- Flights of all planes?
- Catastrophic breakups resulting in shrapnel?

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Image: McDonnel Douglas DC-10 taking off from DFW to ATL.
https://www.surclaro.com/photo3749.html

First let’s remember that the risk assessment did not include the probability of a meteor strike, an on board explosive, sabotage, a missile strike or a mid-air collision with another plane. (or snakes, zombies and vampires for that matter). The assessment was based on the ‘probability’ that all redundant hydraulic systems would be fully disabled by a catastrophic equipment failure. This probability included the failure of the independent paths as well as the single point of failure at the co-location in the two rear wings. There is no publicly available information of which exposure was used.

When the accident occurred the pilot contacted technical services for information on how to fly the plane. Technical services replied that full loss of hydraulics was impossible.

Flight Safety Foundation, Accident Prevention, Vol. 48, No. 6, June 1991, “*United 232: Coping With the “One-in-a-Billion” Loss of all Flight Controls*”, Captain Alfred C. Haynes, United Airlines https://flightsafety.org/ap/ap_jun91.pdf

Assumptions for occurrence of total hydraulic failure

The engines were sufficiently designed to make an uncontained failure almost impossible.

Assumed NO manufacturing or service defects.

Assumed inspection would catch any defects.

The hydraulic line shielding was sufficiently strong to prevent penetration of any uncontained debris.

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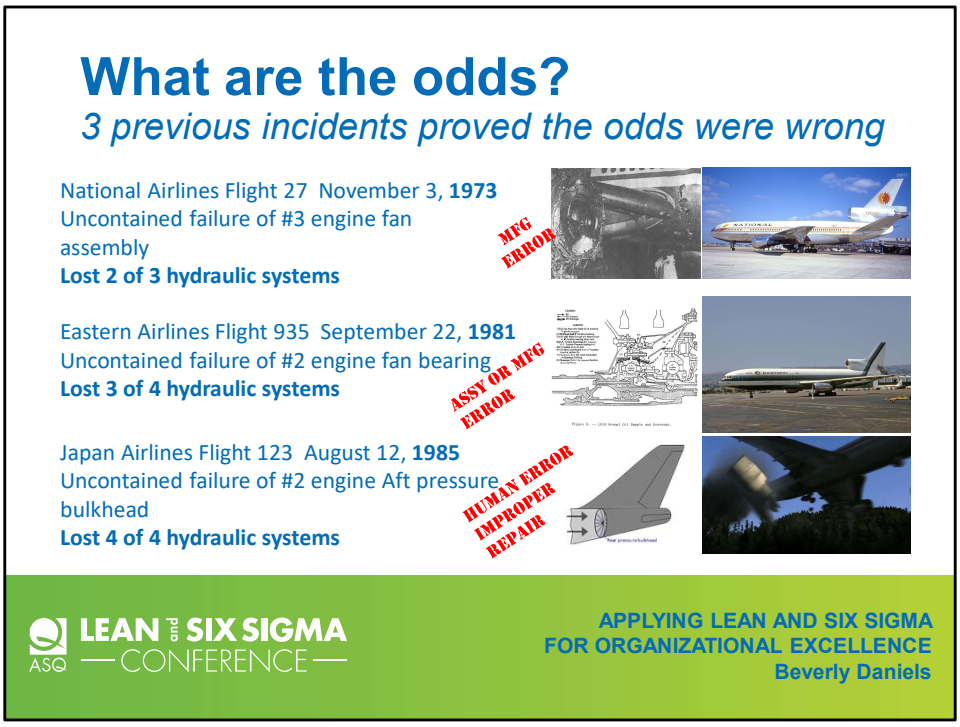


Obviously the shielding wasn't sufficient to protect against debris penetration.

Obviously the assumption of no manufacturing, inspection or service error was wrong.

Even in the face of DATA, the engineers did not change their odds of something going wrong.

https://lessonslearned.faa.gov/ll_main.cfm?TabID=3&LLID=17 Related Accidents/Incidents

Flight 27 Images: McDonnell Douglas DC-10-30 aircraft (N80NA) of National Airlines at London Heathrow Airport Terminal 3 in 1974 (similar to the aircraft used for flight 27) his file is licensed under the Creative Commons Attribution-Share Alike 2.0 Generic license.
http://img26.imageshack.us/img26/9666/nationalengine.jpg Image Shack
NTSB Report AAR75-02
https://www.ntsb.gov/investigations/AccidentReports/Reports/AAR7502.pdf
Flight 935 images:

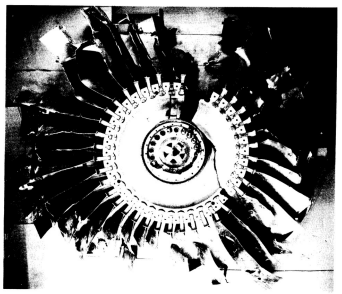
Eastern Airlines N309EA (Aircraft used for Flight 935) photographed June 1973 https://www.jetphotos.com/photo/7713944 Photo https://cdn.jetphotos.com/full/4/70636_1383965519.jpg
RB-211-22B Module Arrangement, NTSB Air Disasters Report AAR82-05 http://www.airdisaster.com/reports/ntsb/AAR82-05.pdf, p. 12
Flight 123 Images: YouTube clip https://www.youtube.com/watch?v=QKENZWQKkz0
"ASN Aircraft accident Boeing 747SR-46 JA8119 Ueno.

Detection Capability?

A **metallurgical defect** was not detected.

The **defect initiated a crack.**

Six service inspections failed to detect the crack.



The length of the crack at the last inspection was ~ ½" in size.

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Image and reference: Aircraft Accident Report, United Airlines Flight 232, McDonnell Douglas DC-10-10, Sioux Gateway Airport, Sioux City, Iowa, July 19, 1989, National Transportation Safety Board, November 1, 1990. NTSB/AAR-90/06.
https://www.ntsb.gov/investigations/AccidentReports/Reports/AAR-90-06.pdf
NTSB/AAR-90/06 PB90-9 I 0406

NASA System Failure Case Studies July 2008 Volume 2, Issue 6.
https://sma.nasa.gov/docs/default-source/safety-messages/safetymessage-2008-08-01-unitedairlinesflight232crash.pdf?sfvrsn=fba91ef8_4

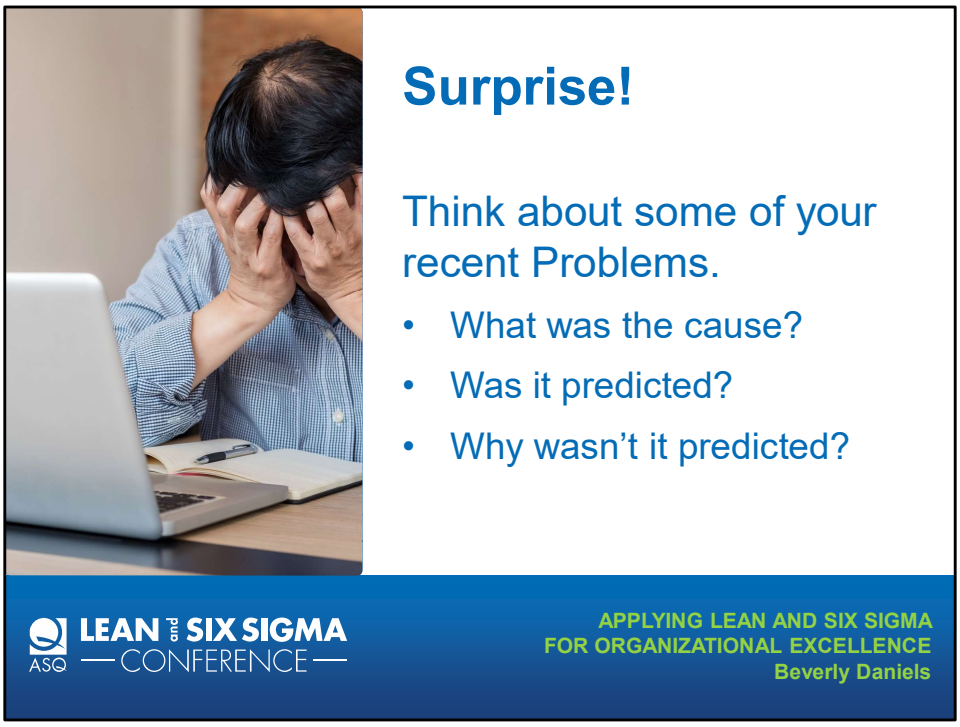

Image: ID 102700573 © Pattanaphong Khuankaew Dreamstime.com

No field escapes were ever predicted. No one said "hey I think something bad is going to happen". Someone did always say "don't worry, what could possibly go wrong"

EXAMPLE

It's just a small change…

4 out of 6 of the last resin changes across multiple plastics suppliers resulted in a product failure.

Another resin change is needed…

What could possibly go wrong?

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Image: https://www.flickr.com/photos/28451803@N00/2414135327

Just another way of saying what are the odds?

So…

What are the odds that the next resin change will result in a failure?

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Image: photo by Nicholas Getty Images

There is no such thing as a small change

There are only large and small effects

Probability, likelihood and occurrence frequency

It's not a static thing; physics happens

- Variation is everywhere.
- Processes have common cause and assignable cause variation.
- Processes change and 'break'.

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In Summary

Severity is an input

Occurrence is an output

Detection is a mitigation

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A Logical Approach to Assessing Risk

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Focus on Function

Create a **function diagram** and process maps as applicable

Create an **input:output matrix**

List **functions**

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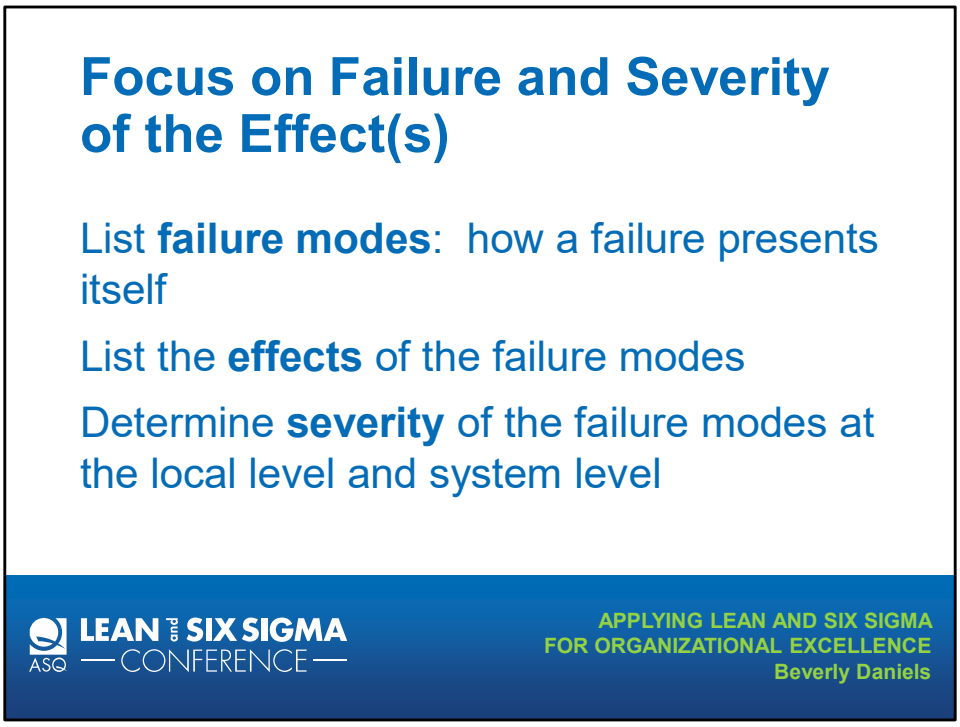

Traditional FMEA teams spend more time debating occurrence and detection ratings and even severity ratings than they do on understanding function and actual functional failure modes. Don't worry about Design and process boundaries. Your product doesn't.

In Design: characterize and mitigate high severity functions

Determine critical input characteristics.

Engineer specifications for critical input & output characteristics.

Develop control plans.

Develop and execute robust V&V test plans to validate design.

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Post Launch: Product changes

Develop V&V test plans for all high severity failure modes.

Well characterized designs may only require first article inspection.

Under-characterized designs require functional testing.

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You MUST understand function

EXAMPLE

Chemistry Analyzer Slide Ink Material Change

The **ink** on chemistry slides was changed to improve bar code readability.

The **addition of silica** to the ink gives it a **matte finish** instead of a glossy finish.

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The chemists know that the **silica will pose no threat to the chemistry** analysis; **no further validation is necessary.** However the ink does other things besides hold the bar code.

Slide Clips

The clip compresses several slides together for months at a time.

There are known problems with ‘sticking’ of the slides in the stack (from various causes) that can cause slide insertion failures.

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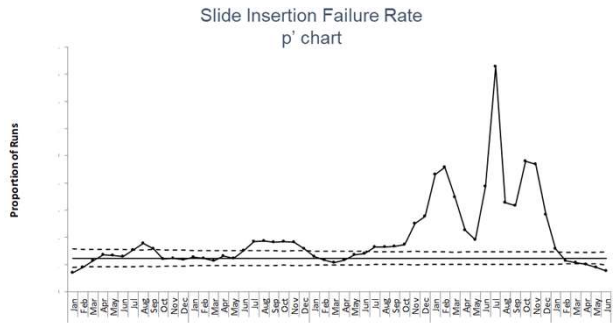
Which occurrence rate would you predict?



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There were several very different causes for slide insert errors during this period. None of them were predicted.
One chronic cause of slide insert errors was the glue sued to fasten the electrolyte slide housing together would 'ooze' out and cause Electrolyte slides to stick together.
The 2015 slide insert error excursion was caused by a change to the ink properties on the laminate electrolyte slide housing just prior to the transition to the molded slides.
These events indicate that ink can be sticky and can cause slide insert errors.
However none of them give any information on the potential occurrence rate for chemistry slides. Nor is there any information that can specify the probability or likelihood of the chemistry slides having a slide insert error rate higher than the baseline. The data only inform us that it is indeed *possible*.

Validation Testing for Slide Insertion Function

k = 6 Instruments spanning various vintages.

Control Level: **2 batches of current ink** ablated on 2 laser lines.

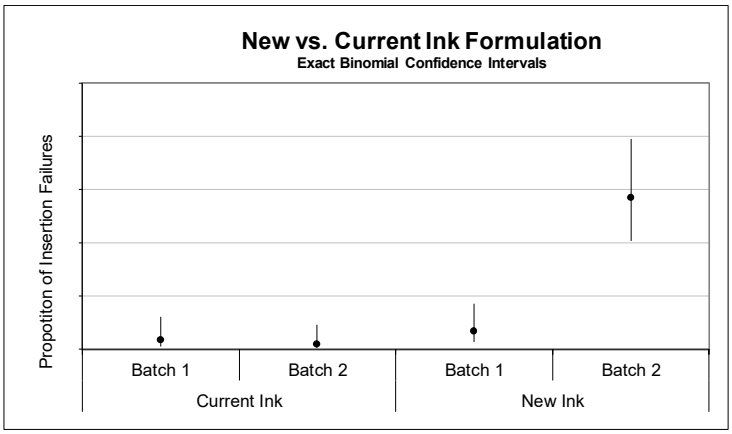
New Level: **2 batches of low gloss ink**.

n = 400 slides per Instrument / Ink Batch.

Tested for bar code read and slide insertion.

n is the sample size
k is the instrument replication size
Each level has 2 independent batches of ink on sldes

And the results were…



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The 2 batches of low gloss ink were produced under 'identical' conditions'.
The causal mechanism was believed to be softer ink (the silica softened the ink creating a more matte finish, which worked well of the original bar code ablation and read Problems).
The softer ink compressed in the clip and stuck to the adjacent slide. Smearing of the ink was also observed on slides that did not fail to insert.

How is Occurrence Determined?

- ✗ Historical data?
- ✗ Opinion?
- ✗ Crystal ball?
- ✓ **Actual Testing**

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You could…

Ignore the violation of sound mathematical principles.

Be disciplined in rating occurrence.

Be diligent in performing effective MSAs

But why?

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But why?

It is a lot of work to avoid guessing, biases and gamesmanship.

And you don't need Occurrence or Detection ratings to effectively manage risk.

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Learning Outcomes

- Understand why RPN values are flawed resulting in incorrect conclusions.
- Understand why likelihood is impossible and irrelevant to assess.
- Accurately assess product changes that might affect quality.

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Active Excursion Risk

Severity, Occurrence and Detection Matter.
RPNs do not.

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Understand the true risk of active excursions

During an **active excursion**, risk assessment is used to decide on immediate, short and long term actions.

This requires actual data, not ordinal rankings.

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Use the Actual Occurrence Rate

Occurrence Rate: the actual or statistically projected occurrence rate.

Consider the non-homogeneity of the failure in the field.

The **unit of measure** for the occurrence rate **must be clearly expressed**: *e.g.* per device, per use event, per hour of use, *etc*.

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Use the Actual MSA R&R Results

Perform an MSA on any screening tests

- **false rejection** rate and cost
- **false acceptance** and escape rate to field

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Assess Customer Detectability

Determine the Customer detection rate and severity of an un-detected event.

Probability statistics may be employed to predict the Customer experience.

But this is often a **subjective qualitative assessment.**

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Develop a Control Plan

Prevent escape (is there a screening method, can we rework, service or replace effectively).

Mitigation for Customer (*e.g.* practice points).

Monitor of Customer experience (*e.g.* smart service control chart).

Response plan if Customer experience worsens.

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Backup and Supplementary Material

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The Case Against the RPN and SO

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Lack of Independence of Occurrence and Detection = Fuzzy Numbers

False acceptance of results near the specification: the larger the measurement error, the more false acceptances.

Interactions make true specifications difficult to determine and accept.

A continuous characteristic that is marginal to a (true) specification limit may falsely pass, yet fail in the Customer's use. This is exacerbated when interactions are present. The larger the R&R variation, the larger the potential false accept events.
Intermittent failures with a small sample size can escape to users.
Visual detection is often directly related to the intensity of the defect. (*e.g.* visual defects that are small or light are harder to detect than large or dark defects)
Occurrence rate estimates based on similar product history is subject to under-reporting by Customers and the use of Customer complaint 'buckets' or causal buckets from Service personnel which obscure the true failure in the data recording method.

Lack of Independence of Occurrence and Detection = Fuzzy Numbers

Intermittent failures coupled with a small sample size will enable escapes.

Visual detection is related to the intensity and occurrence rate of the defect.

Historical occurrence rates are based on under reported data.

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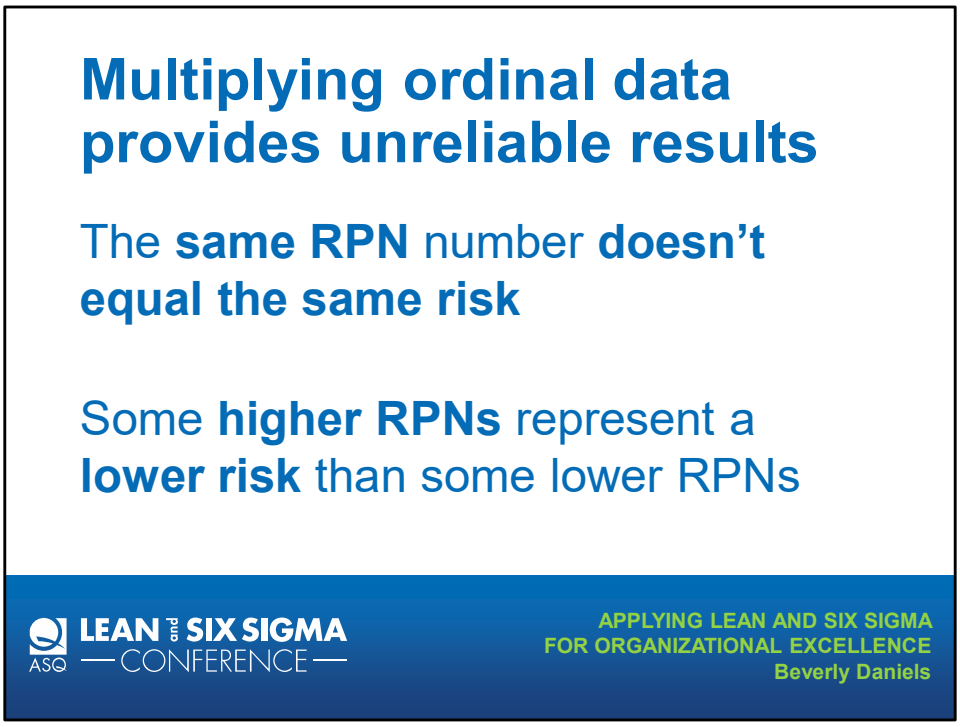
No RPN, No S*O

The ordinal nature of the data results in only a relatively few possible RPN values.

The fuzziness of the data adds to the misleading nature of a single number.

S*O is sometimes referred to as a classification index



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Same RPN, which failure mode is worse?

Failure Mode	Severity	Occurrence	Detection	RPN
A	10	9	4	360
B	4	9	10	360

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The traditional detection scale is opposite from severity and occurrence. A 1 means detection is almost certain and a 10 means detection is impossible

Failure Mode A has a severity of 10 which indicates a serious threat to life and the failure will occur without warning. It has a very high occurrence rating (>1 in 3 or 33% and is “almost inevitable”). The detection ability however, is only moderately high. With this high of an occurrence rate a detection rating of 4 provides very little actual protection; there will inevitably be a substantial number of escapes that are at the highest level of severity. Contrast this with the results for Failure Mode B which has a very low severity (minor disruption, annoying to the Customer if they notice it), a very high occurrence rate and no real way to detect the cause or failure so that the failure is certain to escape to the field. Both have the same RPN, but they are not of the same importance. Clearly a very high severity failure mode whose occurrence level and detection rating ensure that a substantial number of failures (death or serious injury) will occur has a much higher priority than a minor disruption or annoyance even when it is pervasive.

Same RPN, which failure mode is worse?

Failure Mode	Severity	Occurrence	Detection	RPN
A	10	9	4	360
B	4	9	10	360

Failure Mode A: **a serious threat to life**, high occurrence rate (>33%) with a moderate detection ability: **escapes will occur.**

Failure Mode B: **a minor disruption** with a high occurrence rate and no ability to detect an occurrence: **All failures will escape.**

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http://www.qualitydigest.com/inside/quality-insider-article/problems-risk-priority-numbers.html

Different RPNs, which failure mode is worse?

Failure Mode	Severity	Occurrence	Detection	RPN
A	9	7	1	63
B	2	7	10	140

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Different RPNs, which failure mode is worse?

Failure Mode	Severity	Occurrence	Detection	RPN
A	9	7	1	63
B	2	7	10	140

Failure Mode A: **very high severity** with a **high occurrence** rate (5%) and almost **certain detection**: **High scrap and/rework**

Failure Mode B: **very low severity** (probably won't be noticed) high occurrence and no ability to detect: **No effect on the Customer**

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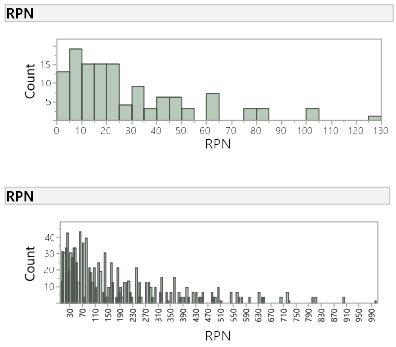
Distribution of RPN Values



Non-uniform distribution of possible RPN values adds to the misinterpretation of the relative importance of different RPN values

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Hints and Tips for Function

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A Day in the Life

The team documents all of the events that the object goes through in it's "life": what the part does and what is done to it.

Shipping & Storage

Assembly

Inspection/Test

Customer interaction: visual and tactile

Use conditions

Specimen interaction and conditions

Functions in use: manual and within an instrument.

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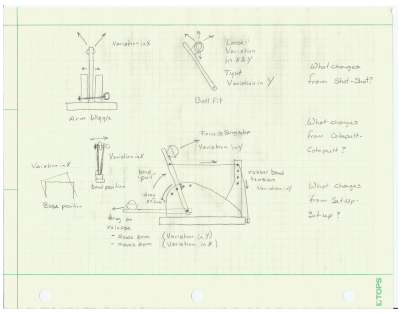
Function Diagram

A function diagram is comprised of a **simple drawing** of the object being changed and how it functions.



What it does and what is done to it

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Simplify, Simplify, Simplify

If you truly understand the function, you can reduce the diagram to simple everyday language that most people can understand.

A simple hand drawn diagram facilitates effective change assessment

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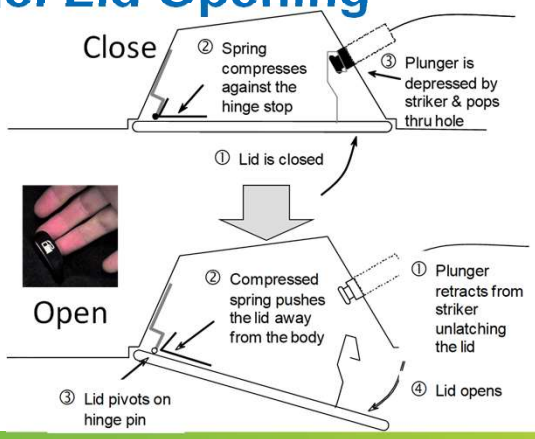
EXAMPLE

Function Diagram: Fuel Lid Opening



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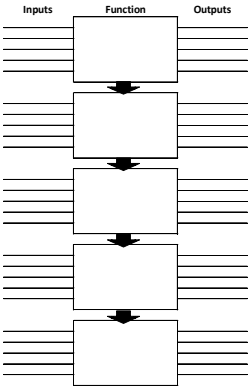
Input:Output Matrix

The input:output matrix lays out the inputs, functions and outputs.

Both inputs and outputs should be **measurable characteristics, properties or features or observable conditions**.

They should not be expressed in vague terms.



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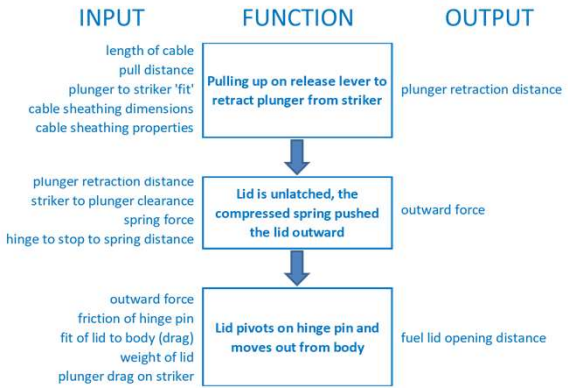
EXAMPLE

Input:Output Matrix
Vehicle Fuel Lid Opening



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Function

The Functions placed on the FMEA are the functions in the input:output matrix. Use the outputs as the description of the function and the start of the failure modes.

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Failure Modes

Identify the potential failures of the identified functions. If the function is in a subcomponent, list both the local effect of the subcomponent function and system effect **as experienced by the customer.**

Complete failure
Partial failure
Intermittent failure
Unintended action

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Effects of Failures

Identify the potential effects of the identified failures from the perspective of:

- The **Customer,** user or consumer.
- The Company: legal, regulatory or tax consequences,
- The Company: reputation, customer defections, *etc*.
- The Company: manufacturing, operations, sales, customer support…

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Hints for Risk Assessment Both Local and System Effects

When determining functions, it is often helpful to start with the **functions of the object within the system** and then identify the **functions of the system** that are affected.

The intent of the assessment is to describe the failure modes, their effect and their severity **in terms of product failure that the Customer experiences**.

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