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Empowerment Quality Engineering

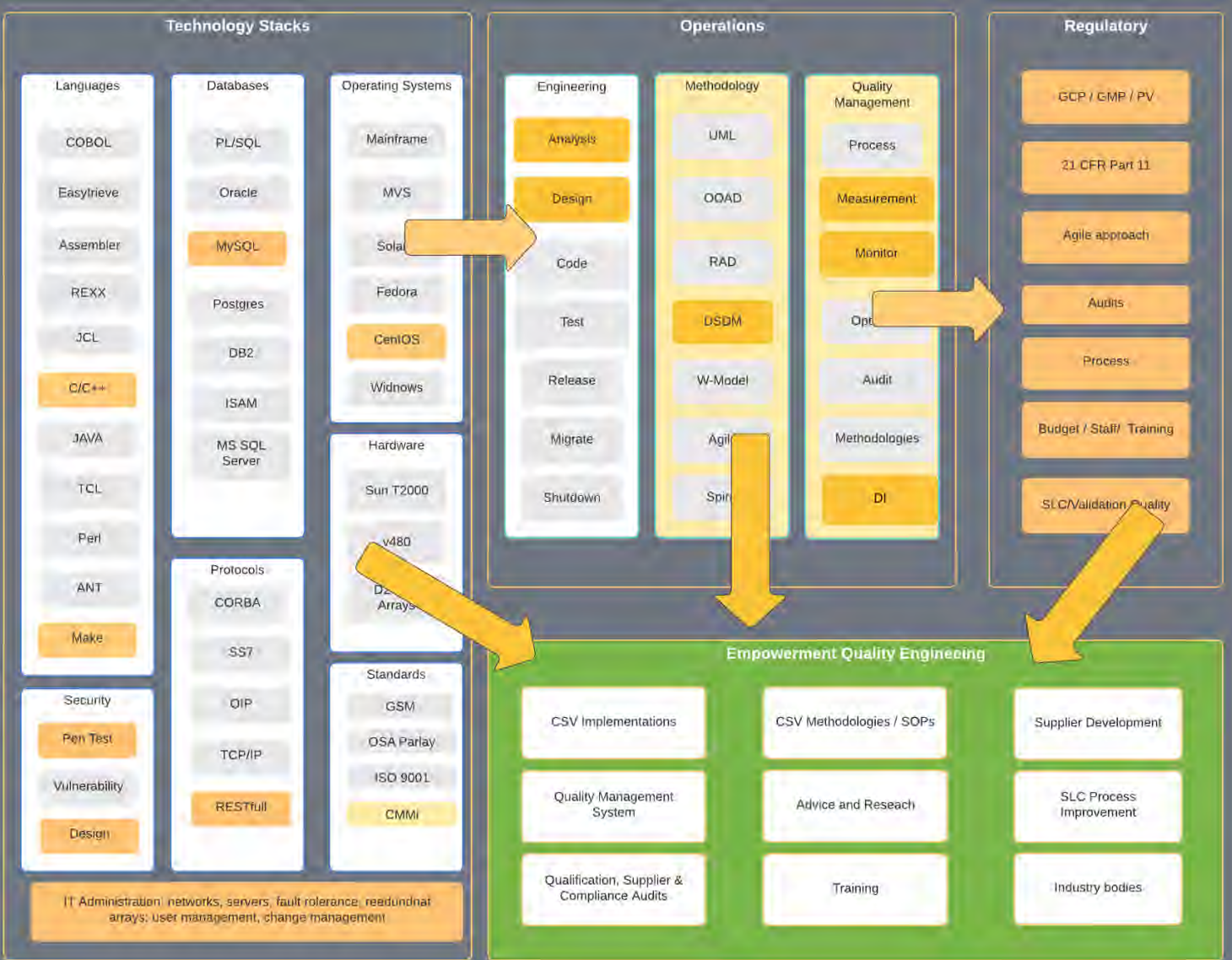
Are we getting quality from Agile?

Agenda

Warning: Vast topic area condensed into 30 mins

- ▶ Introduction: about us.
- ▶ Agile is the only prescription.
- ▶ Brief agile discussion.
- ▶ Quality & metrics.
- ▶ Measuring agile.
- ▶ 2 case studies.
- ▶ Summary.

Surviving 200+ audits



Technologists

Total Quality Focus

Reg Environment



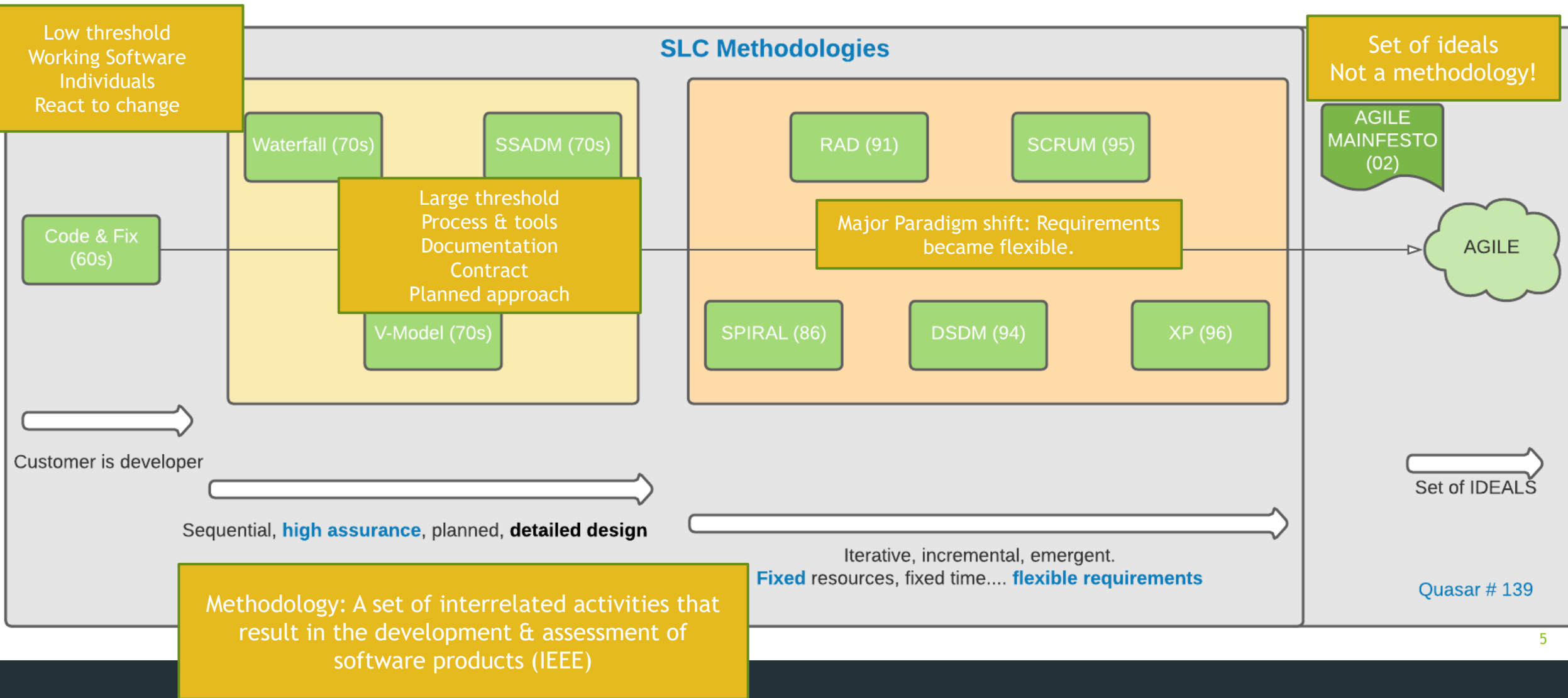
Compliance & Quality is a layered approach

Agile ...the one drug that everyone's prescribed

- ▶ Software lifecycles were designed to cure specific ills of software production
- ▶ Approximately 80+ software methodologies. (Caper Jones)
 - ▶ Each one was prescribed to solve certain problems
- ▶ Yet, Agile is now “the” only prescription in “Supplier” town.
 - ▶ Everyone wants it..?
 - ▶ So, it must be the best approach to meet the needs of our industry....., right?



Brief overview of methodologies...(Quasar #139)



My thoughts on the Agile Manifesto.. <https://agilemanifesto.org>

corporations, Kent Beck tells the story of an early job in which he estimated a programming effort of six weeks for two people. After his manager reassigned the other programmer at the beginning of the project, he completed the project in twelve weeks—and felt terrible about himself! The boss—of course—harangued Kent about how slow he was throughout the second six weeks. Kent, somewhat despondent because he was such a "failure" as a programmer, finally realized that his original estimate of 6 weeks was extremely accurate—for 2 people—and that his "failure" was really the manager's failure, indeed, the failure of the standard "fixed" process mindset that so frequently plagues our industry.



For more agile information see: Agile Working Group discussions:
<http://theRQA.com>:

Quasar #139 – Methodologies.

Quasar #144 – Agile practices & tools.

There was no methodology specified

<https://agilemanifesto.org>

9 out of 14 signatories were structured & design focused software engineers (front load).

<https://agilemanifesto.org/authors.html>

Manifesto born out of “poor management”

<https://agilemanifesto.org/history.html>

Agile suppliers focus on our business needs

- ▶ We have compliance...



- ▶ We can see documentation that reflects the QMS.

QA have oversight of the process.. Right?

- ▶ But we are getting better quality...?
- ▶ Less time on validation?
- ▶ Less volume of releases (defects)?
- ▶ Less help desk tickets?
- ▶ Less security issues?

What business value does a supplier bring?

Now we can't connect to our PV system - we have manually merged data!!

Its 5 months and haven't heard a response on my defect correction!

They keep over writing my previous fixes!!!

What do you mean "prove" we have a good quality?... Our customers love us.. We're #1!

Eh?
No one else says we have to do that... We might consider it when others raise it..

We don't have CAPA's for SLC - you don't understand agile..

Find out how they test - some of the issues we are seeing are poor..

release every 2 weeks... is wrong that we have many bugs to fix... don't need to update...??

Our client's lack instruction?... Nobody else has complained.. Our developers know what to do...we're agile!

We don't show auditors activities because it is our IP and it is confidential.. And we're agile..

That's a traditional auditing question.. We're agile

Why audit us? We have validation documentation. You don't need to audit us!

All software has defects - you can't catch them all!

Very soon we wont be able to recognise our "validation" state.

I have no issue with them ... except that the thing grinds to a halt after 1pm!!!

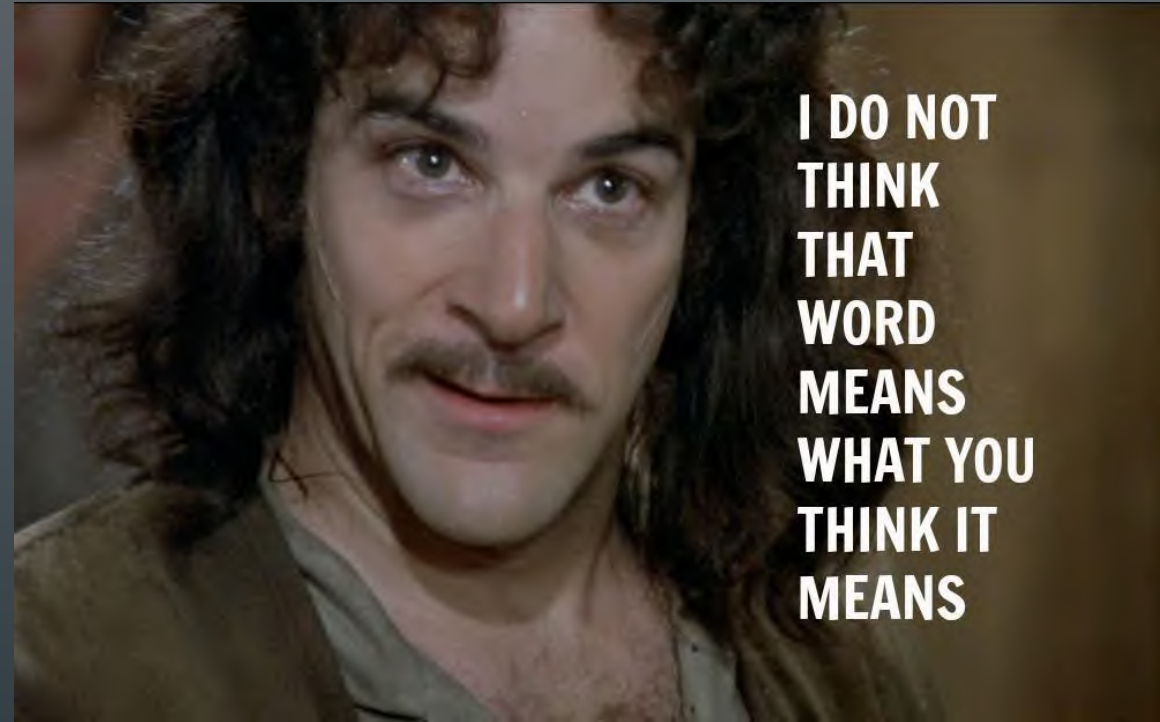
Listen, you don't need to validate - we validate - you just choose to use our system!

Ha ha... our clients have 20 years experience, they need detailed instruction... you don't understand agile...

Too many Defects in Validation.. What are they doing!!

Ask about Quality...

- ▶ Silence is golden
- ▶ ICH Q9/ ISO 9000 : “..fulfils requirements”
 - ▶ But!! Requirements ~ 15% to 20% source of errors/defects (Jones)
- ▶ ICH Q8: “fitness ... intended use “
 - ▶ This can be hard to quantify after the software is released.
- ▶ Words ending in “ility” - reliability & maintainability
 - ▶ Ambiguous. Difficult to quantify.



Need to measure..

- ▶ How do you know if your supplier is in the final race or lagging in the qualifiers?
- ▶ “When you can measure what you are speaking about and express it in numbers, you know something about it” (William Thomson, Lord Kelvin, PLA vol 1. Electrical units of measurement, lecture, 03-May-1883).
- ▶ The reason for measuring software (including service) and the software process is to obtain data that helps us to better control the schedule, cost, and quality of software products/ services.
- ▶ **Metric, software quality.** (IEEE) A quantitative measure of the degree to which software possesses a given attribute which affects its quality



“You cannot manage what you cannot measure” (Anon).

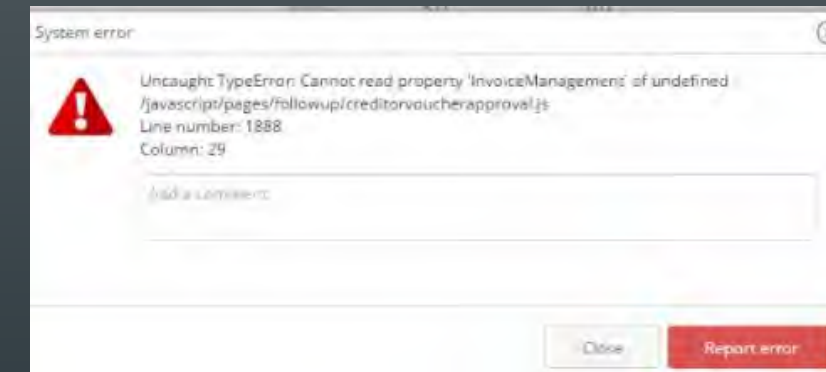
Manage... (for example)

- Process strengths / weaknesses
- Early warning of problems
- Root cause of problems
- Risk based approach
- Waste reduction, rework,... data integrity issues

Metrics: What to measure...

- ▶ Software Defects directly impact the following:
 - ▶ **Reliability**, maintainability, usability, **security**, **data integrity**, fitness for use, conformance to requirements, customer **satisfaction**.
 - ▶ Inverse correlation between software defect levels and user satisfaction - **there is yet to be a software product with high defect levels that is satisfactory to its users.**
- ▶ **Quality: impossible without low defect volumes**
 - ▶ regardless of the quality definition
 - ▶ regardless of the methodology

“(Computerised System) **Quality** is the absence of defects which would **cause the system to produce incorrect results or cause it to fail**”. (EmpowermentQE)



Metrics? But user satisfaction is very subjective

- ▶ How do you know that “User satisfaction” is achieved?
 - ▶ Quality must be measurable when it occurs.
- ▶ How do you know that you are on the right path to achieving quality?
 - ▶ Quality should be predictable before it occurs.

But, I can't predict user satisfaction??
Correlation between defect levels and user satisfaction.
Once we measure then we can predict.
Defects can be predicted.

- ▶ Pre
- bu
- ▶ Def



- ▶ Def

6 The table below gives information about the salts formed when four metal oxides react with acids

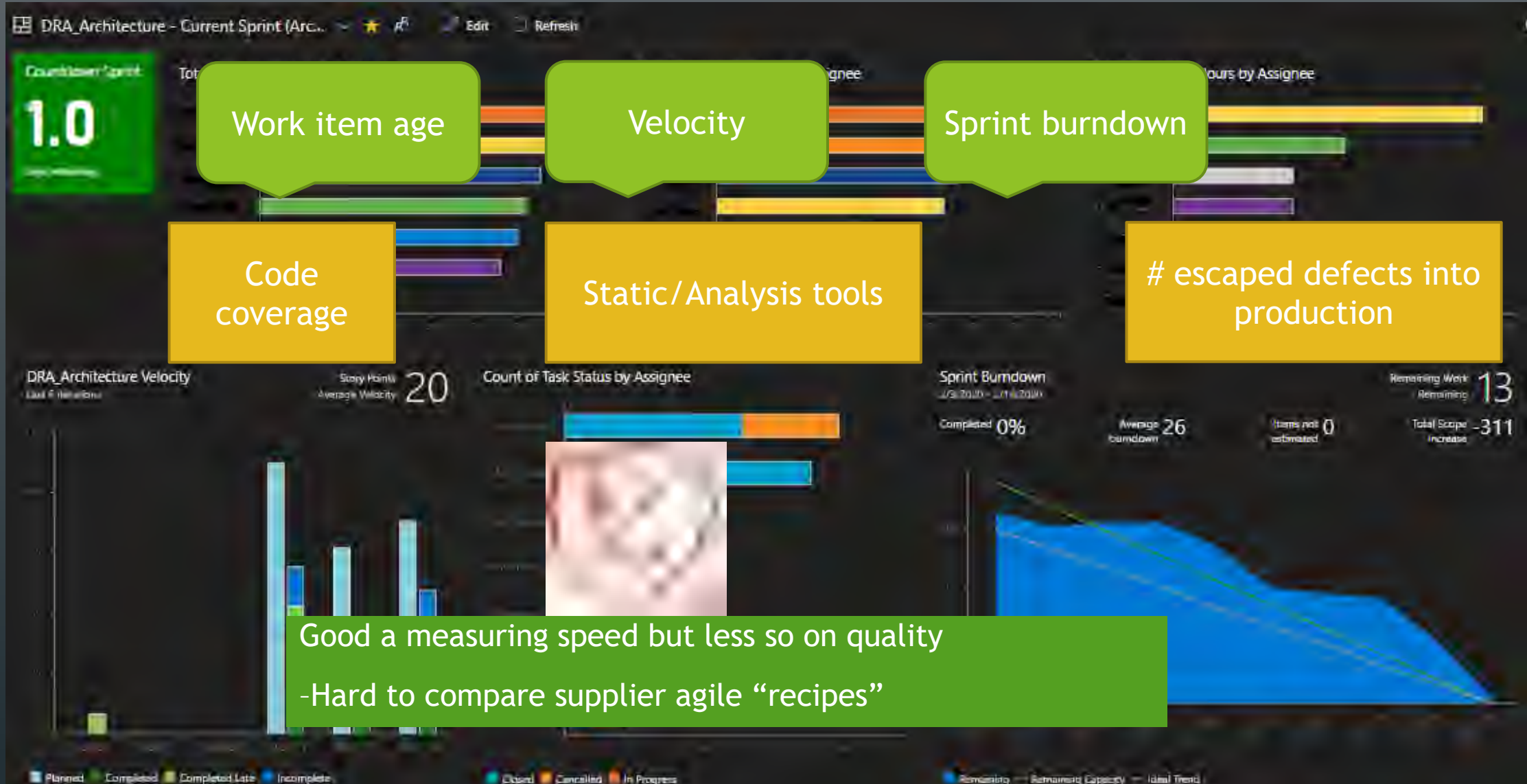
metal oxide	acid used	formula of cation in salt	formula of anion in salt	formula of salt produced
magnesium oxide	sulfuric acid	Mg ²⁺ ✓	SO ₄ ²⁻	MgSO ₄
sodium oxide ✓	hydrochloric acid	Na ⁺	Cl ⁻ ✓	NaCl
copper oxide ✓	sulfuric acid ✓	Cu ²⁺	SO ₄ ²⁻ ✓	CuSO ₄
calcium oxide	nitric acid	Ca ²⁺ ✓	NO ₃ ⁻	Ca(NO ₃) ₂

(a) Complete the table. [4] ✓✓✓✓

(b) Each of these four reactions can be described as neutralisation. Write an ionic equation, including state symbols, for a neutralisation reaction. [3] ✓✓✓

$H^+(aq) + OH^-(aq) \rightarrow H_2O(l)$

Agile metrics: how good is a supplier's agile approach?



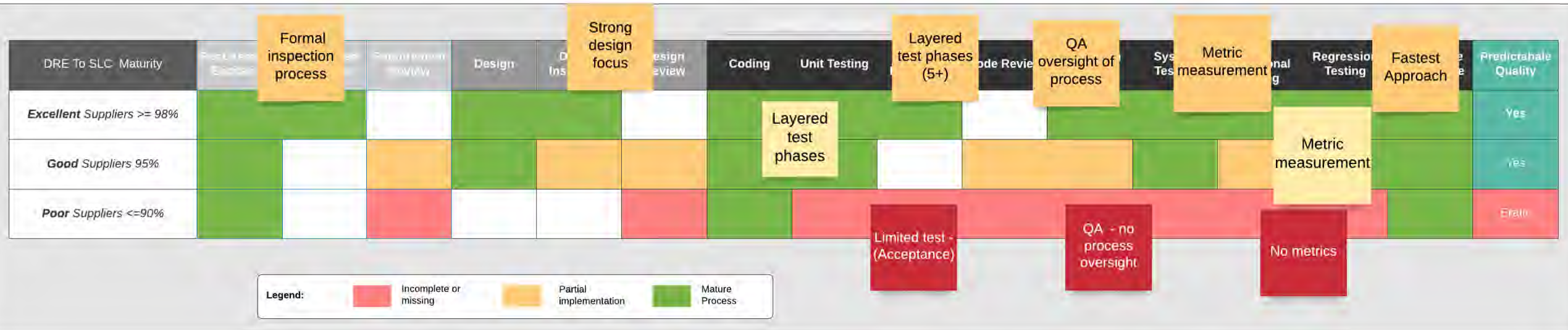
Some defect metrics that can be used

- ▶ Cost | RCA | Software feature / location | Type

DRE Percentage	Supplier is	Notes
▶ $\geq 98\%$	Excellent	Not your suppliers! Aeronautics, Mobile network telephony
▶ $\sim 95\%$	Good	Your Supplier?
▶ $< 90\%$	Poor	Your Supplier?
		Source: Caper Jones

- ▶ Supplier process: 90% DRE (90/100)
- ▶ [Collaborative approach] Supplier & Validation: 95% DRE (95 / 100)

SLC process implementation are indicators to DRE



Example #1: PV Safety SaaS Supplier: Agile

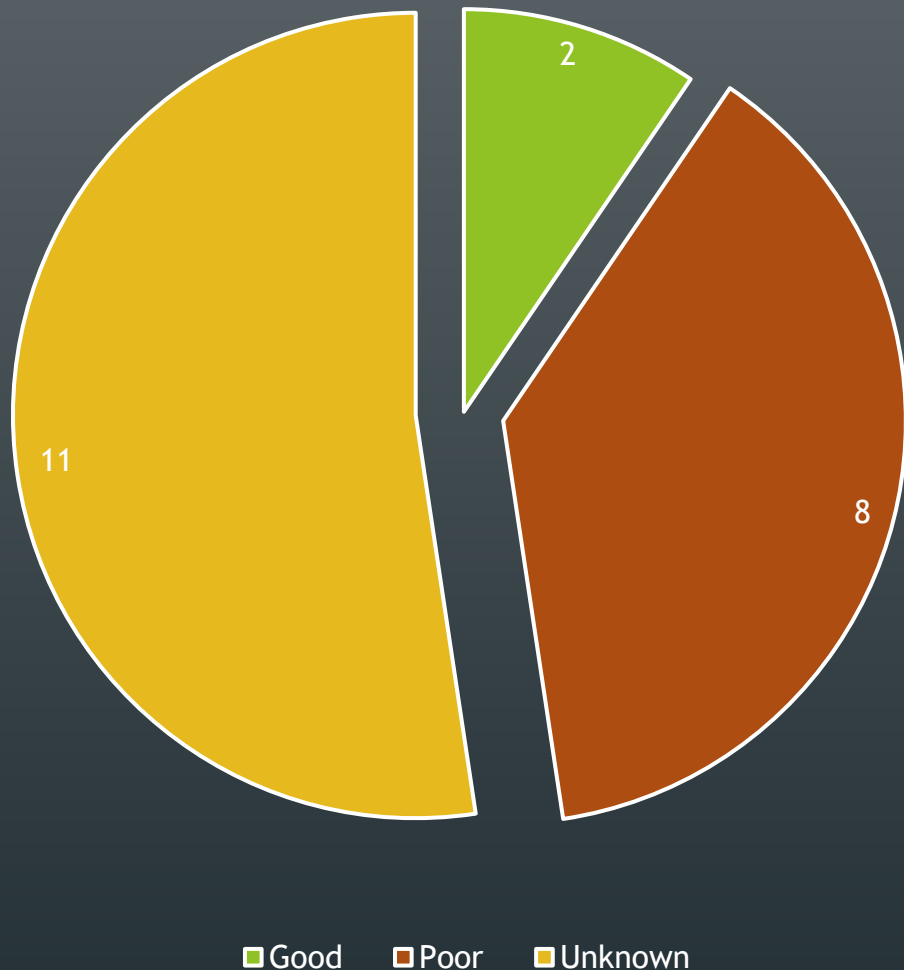
Compliance aspects	Quality aspects
<ul style="list-style-type: none"> • QMS: SOPs WI's Guidelines across SLC. • QA Overview: CAPA process. • Traceability. • Code review. • Unit testing. • Independent testing. • Created "documentation" • Compliant to their QMS. • Supports Validation approach 	<ul style="list-style-type: none"> • Technical instruction located in Wiki's <ul style="list-style-type: none"> • No QA oversight. • Erratic description/adherence between • DRE - 83% • Narrow test focus • Poor front loading • Prolonged Validation • Production issues • Customer to perform pre Validation testing phase to ascertain quality for each release. • High # of defects in production.

Example #2: Global CTMS SaaS Supplier: Agile

Compliance	Quality
<ul style="list-style-type: none"> • QMS: SOPs WI's Wiki's • Themed internal audits on specific processes - instructions reviewed in audit!! • Requirements risk a • Traceability • SEPG group • Multi-layered indep <ul style="list-style-type: none"> • Integration sy • usability secu • static /dynamic • Limited release cyc • Concise documentation for customer understanding. • Compliant to their QMS 	<ul style="list-style-type: none"> • Out of date design • Missing design process or unit testing process <div data-bbox="637 549 1770 1028" style="background-color: #FFD700; padding: 10px; border: 1px solid black; margin: 10px;"> <ul style="list-style-type: none"> • DRE - 95% • Answered question: "how good is your process" • Active measurement & improvement • Knew next stage of their process evolution • Low # of production defects </div> <ul style="list-style-type: none"> • System testing • Integration didn't discuss • The effectiveness of • Types of issues found • The severity of defects • Collected by Certified • Concurrent process improvement: Unit testing

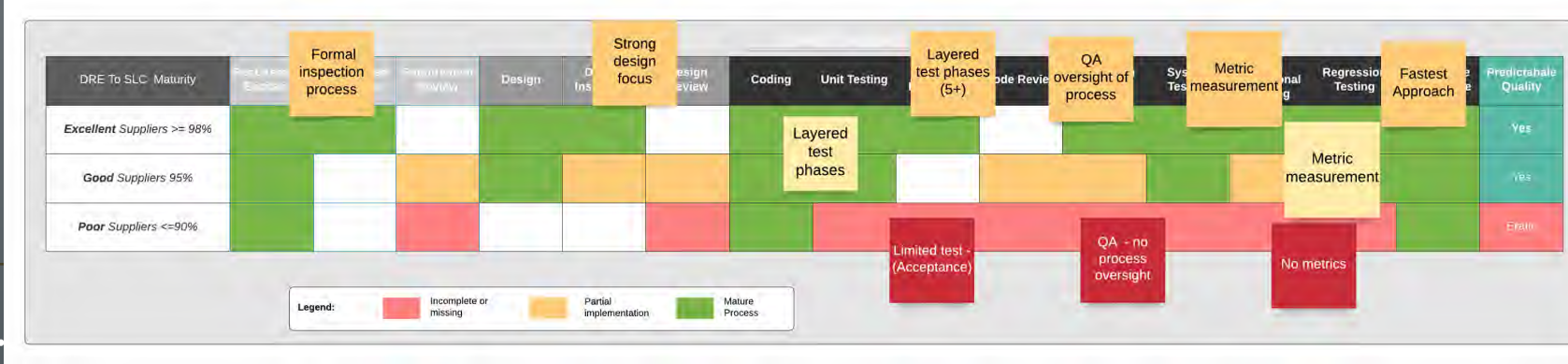
Last 21 Audits

These trends are indicative of suppliers regardless of approach over the last 10 years.



- ▶ 2 suppliers (1 actively measuring metrics & 1 with metrics in place)
 - ▶ DRE of ~95%.
 - ▶ Agile: Good range of SLC processes.
 - ▶ Technical processes are defined with QA oversight.
 - ▶ Predictable, on time releases, low severity issues.
 - ▶ Stress free & limited validation.
- ▶ 8 had a DRE of ~83 to 87%...
 - ▶ Derived from defect collation from internal tools | summary report | customer validation | production defects.
- ▶ Remainder did maintain defect metrics
- ▶ Trend: Problematic releases
 - ▶ Agile approach with big gaps in SLC processes
 - ▶ Irate customers: Heavy validation workload
 - ▶ Production Issues...
- ▶ Multiple releases of “features” for customers
 - ▶ 80%+ involved defect correction: Technical debt - quality not performed (speed).

The state of affairs: 2021



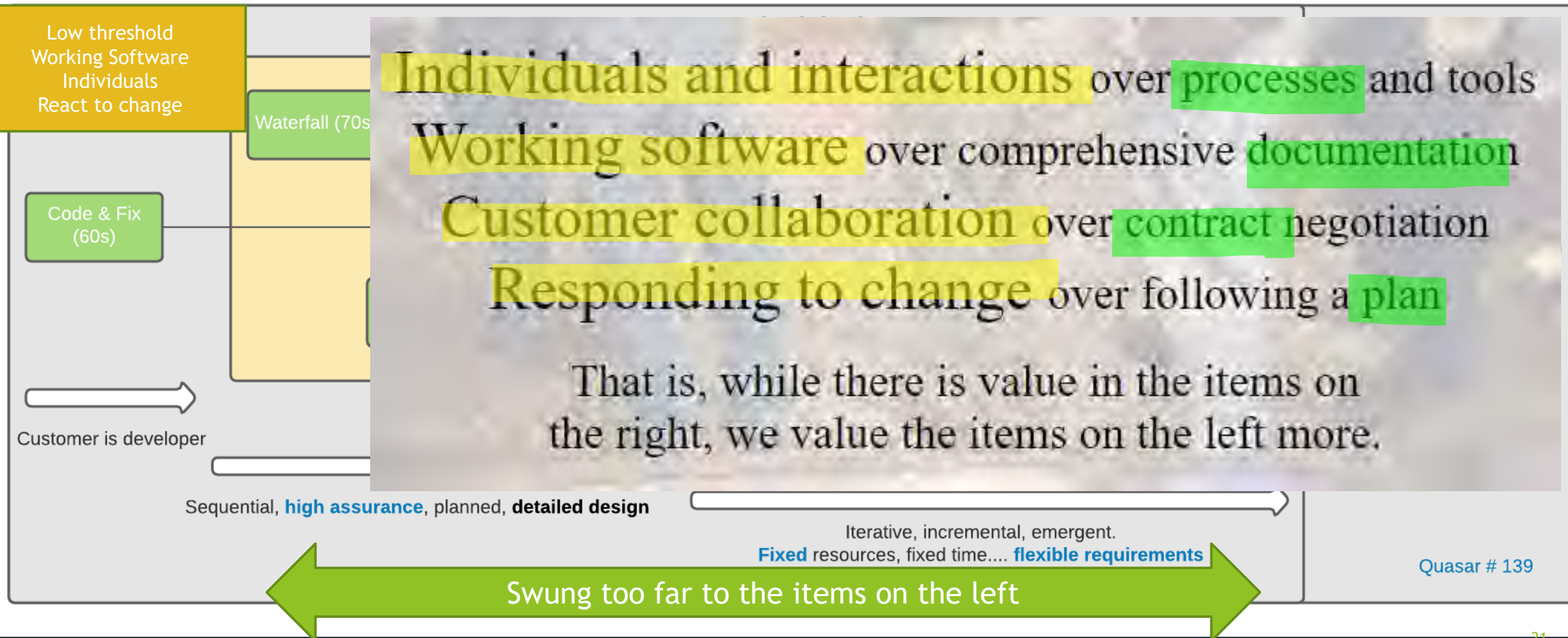
- ▶ Agile can deliver good quality.
 - ▶ Aggregation of technical process across the SLC.
 - ▶ Good software practices are applicable regardless of “methodology”.
 - ▶ Is it the best?
 - ▶ Faster Delivery: Combined Requirement Models and code generators (Jones)
 - ▶ Better Quality: Rational Unified Process - 99% DRE (Jones)
- ▶ Is our industry getting quality from Agile?
 - ▶ **No.** Lack of supplier improvement from last 10 years
 - ▶ Compliance to supplier’s QMS may not equate to CS quality.
 - ▶ Long term Business Process Owners found **NO ADDITIONAL BENEFIT** from Agile process!
 - ▶ “Quality” & Service is poor. **Remember: Correlation between defects and user satisfaction**

Need to understand the “recipe” of the agile methodology and measure it.

- ▶ Measure available metrics and ascertain who are “good” suppliers and who are “poor”.
- ▶ Next audit:
 - ▶ Ask the question “how good is your process?”
 - ▶ Ask for defect metrics for the last 3 supplier releases and from the validation reports and from the production ticket system - find the DRE.
- ▶ Encourage suppliers to use metrics.
 - ▶ Low hanging fruits will be available to improve DRE.
- ▶ Add metrics to your contracts.
- ▶ DRE measures your supplier’s SLC Quality Assurance activities:
 - ▶ > DRE == > quality assurance performed.
 - ▶ You **can’t apply CSA approach without measurement** of SLC effectiveness.
 - ▶ 1 or 2 test (replicated) test phases won’t achieve this.



Agile Equation: Misuse will revert to old problems



Need to swing the pendulum back for a more balanced approach

