Freshening up your Internal Audit programme

Ian Hendra
Director, Clearline Services Ltd
ian.hendra@clearlineservices.co.nz

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Finding better business solutions…

Internal audit

This webinar is for the strugglers…

- ✈ Do you wonder why on earth it's necessary?
- ✈ Does it <u>really</u> tell you anything you didn't know already?
- ✈ Do your people enjoy it?
- ✈ Do you do it to keep the auditor at bay?
- ✈ Top managers "too busy running the business"?
- ✈ Are your auditors are the only fans?

How good would it feel if you could get a better bang for the buck?

Three topics

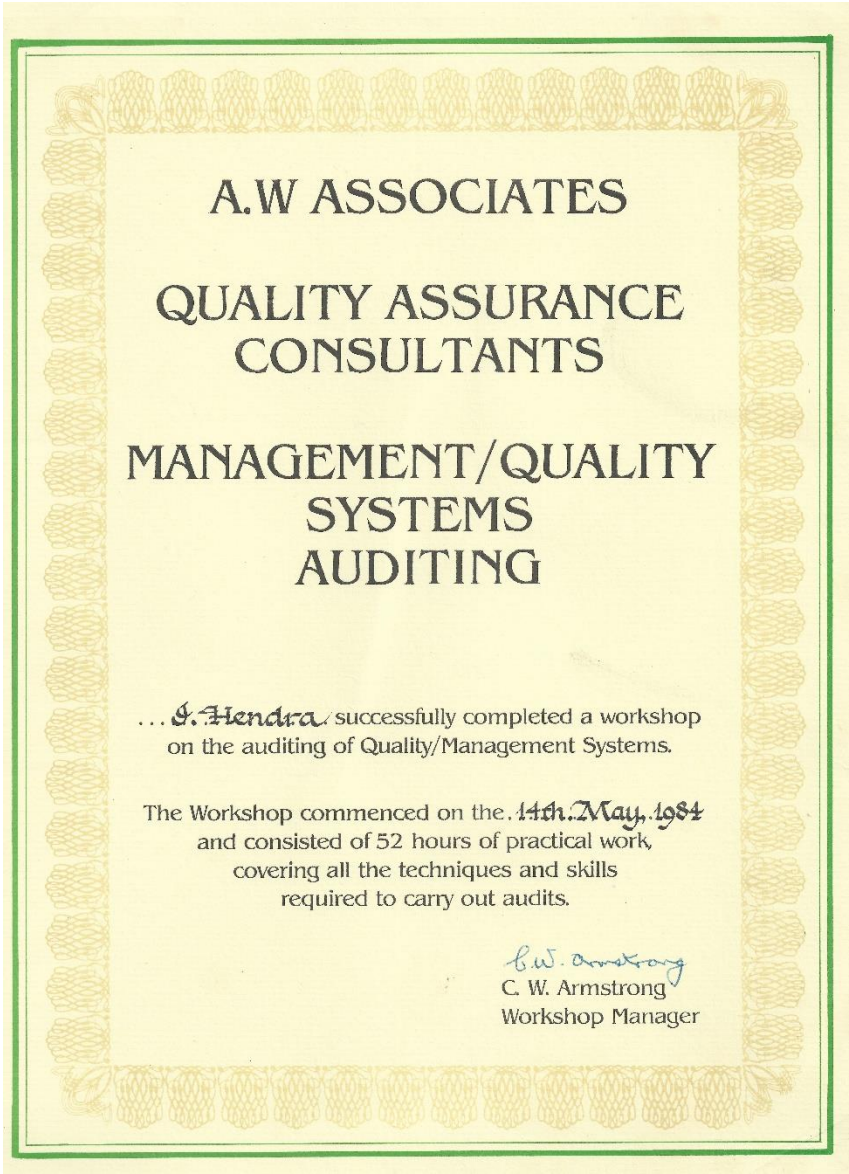
- History….according to me, anyway..
- What's wrong with the conventional approach?
- A better way…

History…

- DHSS NHSPD STB6A
  - 1000 installation audits in 7 years….1977-84

14 May 1984

- Alex McIntosh & Charlie Armstrong
  - 52 hours that changed my career…
- Who were they?
- What was it all about?



A.W ASSOCIATES

QUALITY ASSURANCE CONSULTANTS

MANAGEMENT/QUALITY SYSTEMS AUDITING

…S. Hendra successfully completed a workshop on the auditing of Quality/Management Systems.

The Workshop commenced on the 14th. May. 1984 and consisted of 52 hours of practical work, covering all the techniques and skills required to carry out audits.

C. W. Armstrong
Workshop Manager

QA = EM

- DHSS Manufacturer Registration scheme..
  - DHSS GMP (Medical Devices) Guides included BS 5750:1979:Part 2

QUALITY ASSURANCE

=

EFFECTIVE MANAGEMENT

But not one single solitary word about "internal auditing"!

NATO, AQAPs & DEFSTANs

- NATO Committee AC 250 – 1955
  - Tactical problem – how to select suppliers?
- Allied Quality Assurance Procedures (AQAPs) 1969
  - Quality has to be designed in from the start..(can't inspect it in later, nor audit it in for that matter, I'd say…)
- Defence procurement via (1972 UK version) DEFSTAN 05-20 series applied to individual contracts..
- Three levels..
  1. Design/Production/Supply = prime contractors (relatively few),
  2. Production/supply = their sub-contractors (thousands..),
  3. Supply only = their stockists etc (many…),
- ..but 2 & 3 were kept ignorant of the prime contract.

And not one single word about "internal auditing"!

BS 5750:1979, UKNQC

- 1979, DEFSTANs become BS5750:1979, Parts 1, 2 & 3
  - (Rear Admiral Derek Spickernell as DG of BSI)
- 1984 = UK National Quality Campaign
  - DTI White Paper – Standards, Quality & International Competitiveness
- Five key elements
  1. BS 5750:1979 will sort out the lousy quality
  2. Set up register of consultants
  3. Provide big budget for consultancy grants so UK companies can get certified
  4. Enable an external certification service,
  5. Set up "Accreditation" to maintain standards and protect against collusion between CBs and companies in claiming grants (they called it "conflict of interest").

And still not one single word about "internal auditing"!

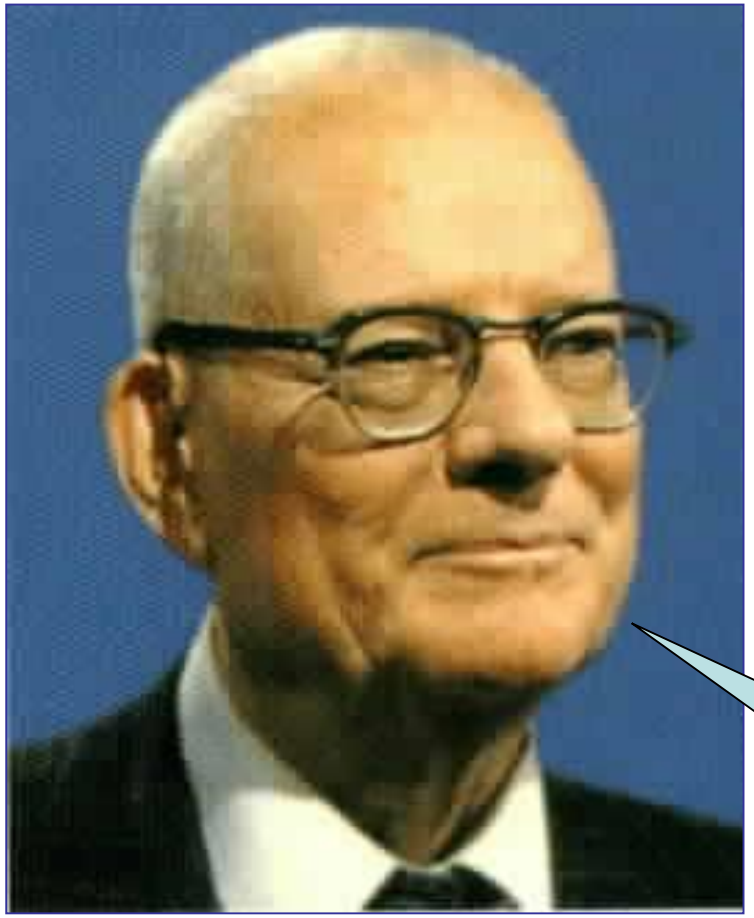
1988…

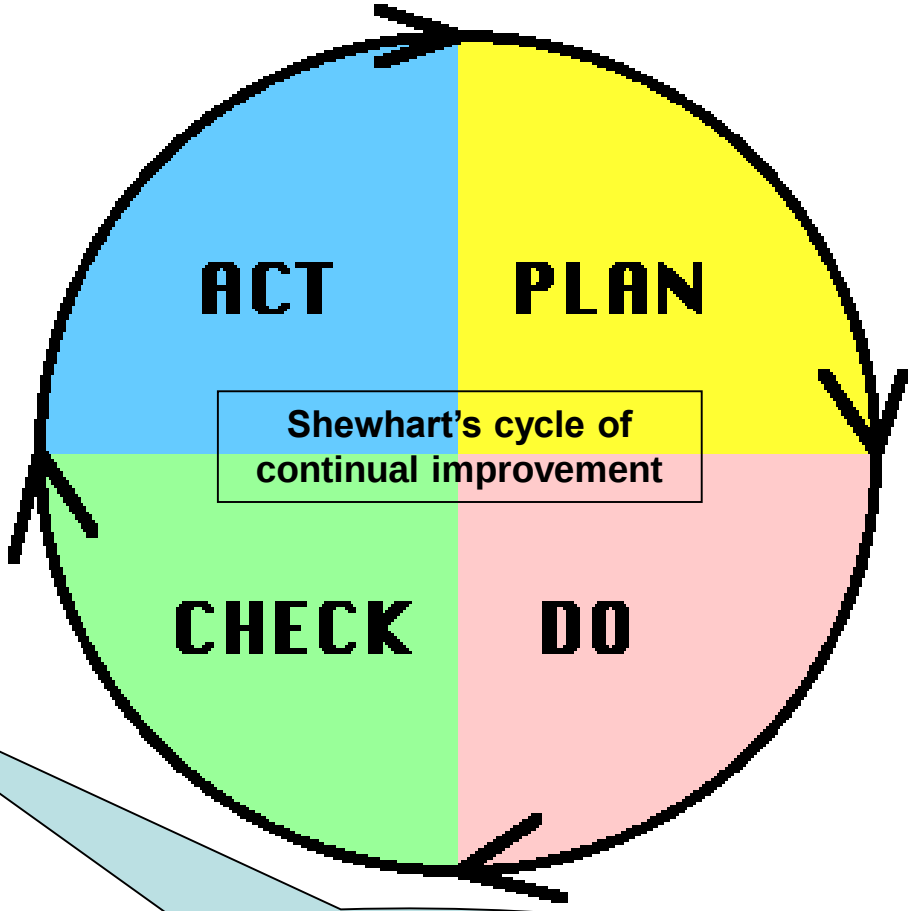
- 1988 Ian joins an accredited CB thingamajig as their first QM…
  - 30 certs when I joined, 1500 more over the next 3 years..
- 1987, ISO 9001, 9002, 9003 appeared
  - Almost identical to BS 5750:1979, inc levels 1, 2 & 3
  - Includes Internal Audit (WOSSAT???)
  - Came from nowhere….I had to suss it out for my CB…
  - Final Inspection & Test disappeared…
- The industry only knew about external contractor assessment auditing,
  - So it stuck to its knitting (still THE problem today..)
- ISO 19011 appeared eventually
  - But hasn't really changed the question & answer "Don't lie, show me!" approach that external auditing inevitably demands.

Internal Audit does not feature in

- Lean Six Sigma, except as a way to investigate how better to lay out a workspace..
- Business Excellence (Baldrige)
- Zero Defects
  - In *Quality is Free*, Phil Crosby said *"Few functions are spoken about more and understood less than auditing. It is often the last refuge for those who really don't know how to run a prevention-oriented life."*
- TQM, Dr Deming didn't mention it on his 4 day course..
- Dr Juran's tome, Quality Control Handbook says almost nothing either…

Dr W Edwards Deming (1900 - 93)





14 Points for the Transformation of Management

Breaching 6 of Dr Deming's 14 Points

1. (Point #3) Cease dependence upon inspection, build quality into the product in the first place – can't audit it in either, conventional IA method misses the point
2. (Point #5) Improve constantly and forever the system of production and service – not just at defined intervals
3. (Point #8) Drive out fear, so that everyone may work effectively – confrontation is pointless
4. (Point # 9) Break down barriers between departments, people must work as a team to foresee problems - – so having departments audit each is other is counter-productive, misses the point..

✈ ……..

Breaching 6 of Dr Deming's 14 Points

- ……

5. (Point 10) Remove barriers that rob workers of pride of workmanship – so don't have internal auditors second guessing them..
6. (Point 11) Remove barriers that rob people in management of their right to pride of workmanship – so don't have internal auditors second guessing them either…

- Instead, substitute leadership and a vigorous program of education and self improvement for everyone
  - One way is to establish properly resourced cross functional teams to break down silos..

ISO 9001:2015/9.2 Internal Audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) the organization's own requirements for its quality management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

- Three processes that might be novel…re the above..
  1. a) 1) Require managers to commission investigations to validate conformity in areas where they have concerns *(eg via a standing agenda item on team meetings)*
  2. a) 2) Set up a DIME matrix vs the standard (eg with an annual check audit),
  3. b) Use cross-functional team based brain-storming tools from the Memory Jogger 2 within routine process, product and project review procedures.

DIME matrix

"Exposition of conformity"

- Only one item of conformity per row, (224 in ISO 9001:2008)
- Uses only the words of the standard,
- 7 columns
  1. Row number,
  2. Item,
  3. Documented where?
  4. Implemented how?
  5. Monitored how/by whom?
  6. Evidence what/where?
  7. Note (for audits etc)
- NOTE: Every row becomes a documented procedure!

Example ISO 9001/5.6 (2008)

"Documented" means Where, how & current?	"Implemented" means Processes & records?	"Monitored" means Data used how, by whom?	"Evidence" means evidence of effectiveness	Red Applicable, not evident	Amber Applicable, not convinced	Green Applicable, looks OK	Grey Not Applicable

5.6 MANAGEMENT REVIEW

5.6.1. General

#	Question	Documented?	Implemented?	Monitored?	Effective?	RAG flag
49.	Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?					
50.	Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives?					
51.	Are records from management reviews maintained (see 4.2.4)?					

5.6.2. Review Input

#	Question	Documented?	Implemented?	Monitored?	Effective?	RAG flag
52.	Does the input to management review include information on: a) Results of audits?					
53.	b) Customer feedback?					
54.	c) Process performance and product conformity?					
55.	d) Status of preventive and corrective actions?					
56.	e) Follow-up actions from previous management reviews?					
57.	f) Changes that could affect the quality management system? and					
58.	g) Recommendation for improvement					

#	Question	Documented?	Implemented?	Monitored?	Evidence?	Note
279	Are records of all customer complaint investigations maintained (see 4.2.4)?	1. 791-Customer complaints & issues 2. 792-Quality Manager's review of tickets and complaints		1. CEO, 2. PST Team 3. Q & R Manager	• Customer records in Zoho	**IR 493**
280	If investigation determines that the activities outside the organization contributed to the customer complaint, is relevant information exchanged between the organizations involved (see 4.1)?					
281	If any customer complaint is not followed by corrective and/or preventive action, are the reason authorized (see 5.5.1) and recorded (see 4.2.4)?					
	CMDCAS req't Do the Manufacturer and its Canadian importer and distributors maintain records of reported problems or consumer complaints relating to the performance characteristics or safety of the medical device? Are these problem reports or consumer complaints used as input into the corrective and preventive action system? (CMDR 57 (1)(b))	1. 791-Customer complaints & issues 2. 792-Quality Manager's review of tickets and complaints	1. CEO, 2. PST Team 3. Q & R Manager	Customer records in Zoho		Need to deal with the "outside the organisation" issue at 280.
282	If national or regional regulations require notification of adverse events that meet specified reporting criteria, has the organization established documented procedures to such notification to regulatory authorities?	1. 804-Informing approval agencies of changes affecting our status 2. 805-Reportable occurrences - issuing an Advisory Notice		1. SP/Production&Support Team 2. Q & R Manager	SP/Regulatory/SiteContents/AdvisoryNotices	**IR 493**
	CMDCAS req't Do the Manufacturer and its Canadian importer have documented procedures to inform Health Canada of incidents that meet the mandatory reporting criteria found in Sections 59 to 62. Note 2: For guidance on mandatory problem reporting see http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index_e.html	1. 1081-Distributor Management 2. 804-Informing approval agencies of changes affecting our status 3. 805-Reportable occurrences – issuing an Advisory Notice.		1. CEO, 2. VP Sales & Marketing 3. Q & R Manager	• Zoho customer records • SP/Regulatory/AdvisoryNotices • SP/Management/Distributors	

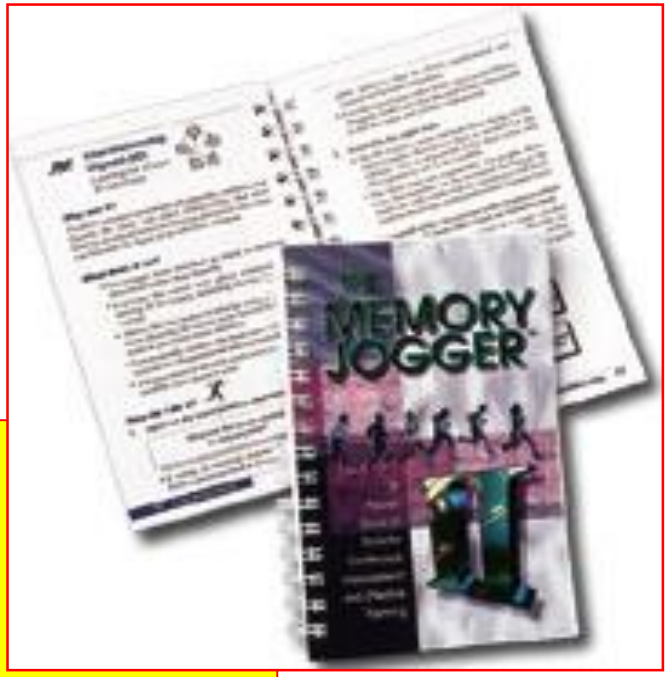
- Example, ISO 13485:2013, 297 items
  - Yellow on right = audit finding (an IR is an Improvement Report)

Developing the skills

GOAL/QPC Memory Jogger II tools

1. **Affinity Diagram**
2. **Interrelationship Digraph**
3. **Tree Diagram**
4. **Prioritisation Matrices**
5. **Matrix Diagram**
6. **Process Decision Program Chart (PDPC)**
7. **Activity Network Diagram**

The 7 Management & Planning tools
(from QFD)



A. **Flow charts**
B. **Run charts**
C. **Control charts**
D. **Histogram**
E. **Scatter Diagram**
F. **Pareto diagram**
G. **Cause & effect diagram**

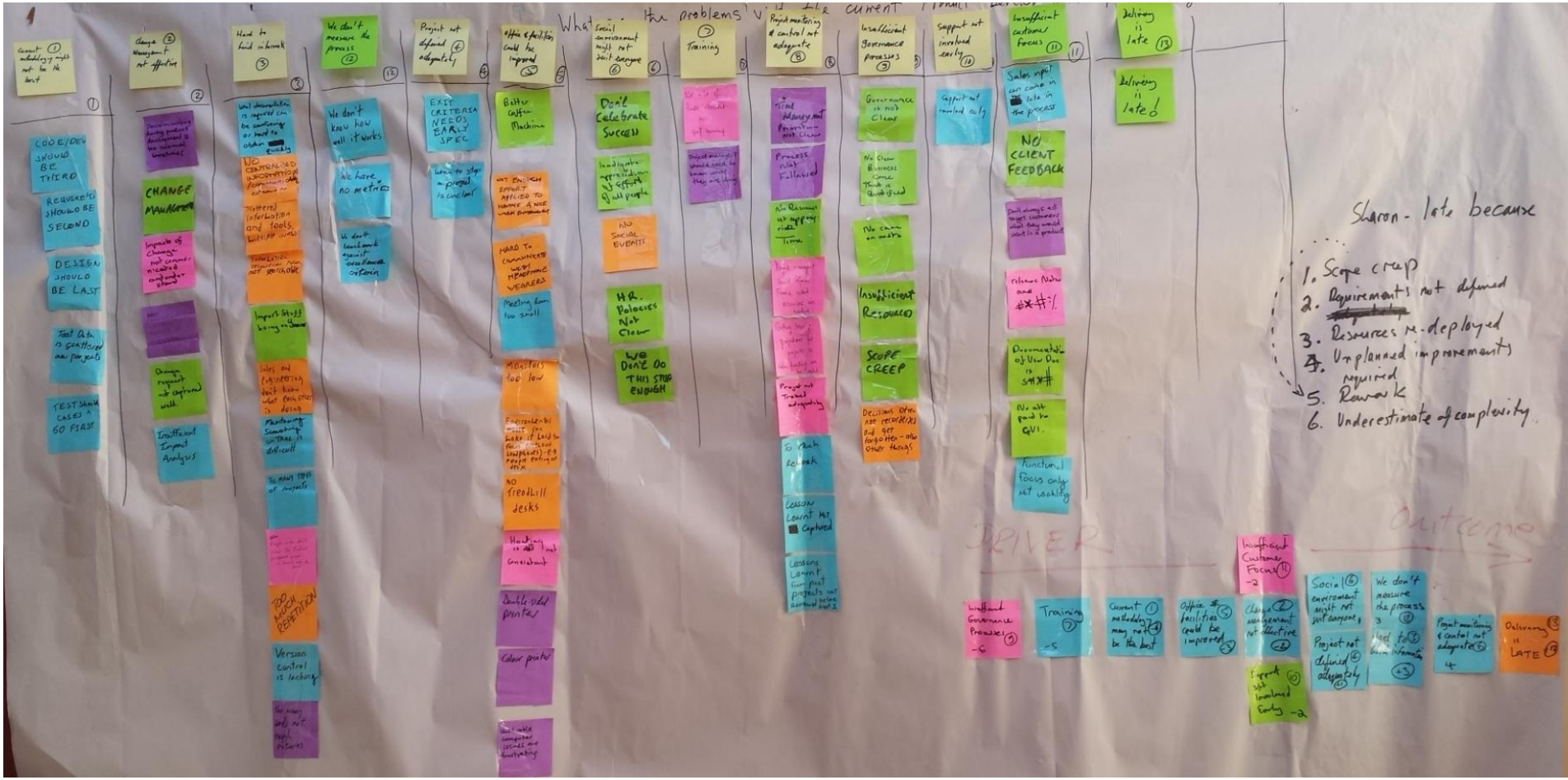
The 7 Quality Control tools
(Dr Deming's original SQC tools)

Affinity Diagram

Process:

1. Set up room, Wall Sheets, PostIts, Vivids
2. Assemble cross functional team
3. Agree the wording of the question
4. Agree brainstorming rules,
5. Facilitate plenty of discussion, answers on PostIts,
6. Place PostIts at random on the wall sheets
7. Facilitator makes sure all have their say,
8. When discussion has stopped,
9. Group approaches wall sheets to sort the PostIts into columns IN COMPLETE SILENCE
10. Group then writes Summary headers that reflect each column.

Affinity Diagram

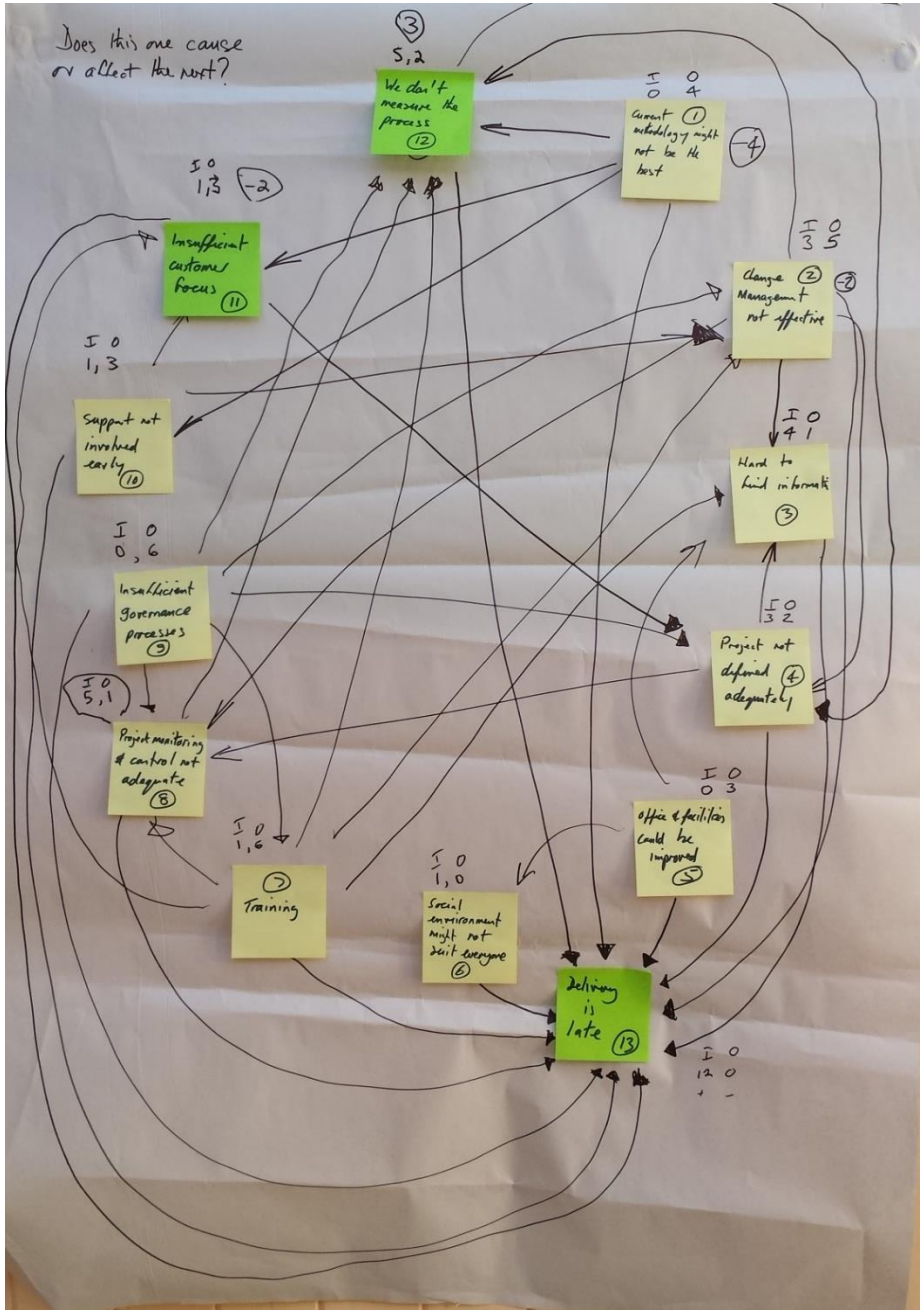


What are the problems with the current product development process?

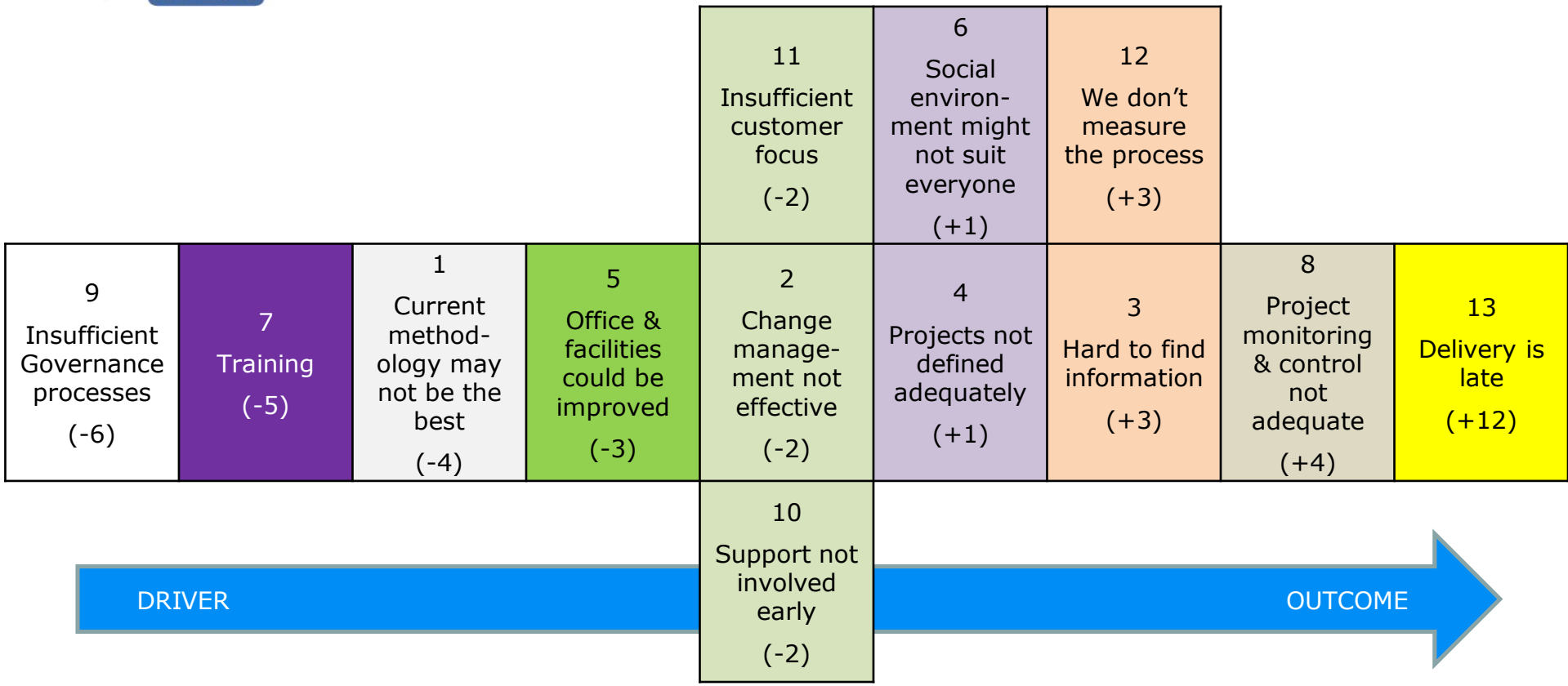
Interrelationship digraph

From the AD,

- Place summary headers in a circle
- Agree the question
  - Does this header cause or affect the next?
- Process
  1. If Yes draw outgoing arrow
  2. If No, draw nothing, go right round 360..
  3. Count Outs and Ins
  4. Ins – Outs = Scores
     - Highest +ve is Main Outcome
     - Highest –ve is Main Driver



Overall audit result



- 14 people involved,
- 2 x 2 hour sessions, everybody engaged in the process and enjoyed it.
- 69 answers to the AD question, 13 Summary Headers for the ID
- Led to change in office premises and 30+ changes to the PD process itself within the next 6 months.

Summary

- IA came from nowhere
  - It lets Management off the hook..
  - Management is responsible for conformity and system effectiveness - PERIOD
- It's an ISO peculiarity
  - other schemes don't bother with it
- It's worthless if it adds no value
  - So use it as a tool
- Using the semi-confrontational external audit methodology hides the potential
- Using fully inclusive team tools works much better

Thank you

Look all around, there's nothin' but blue skies

Look straight ahead, nothin' but blue skies….

I can see clearly now, the rain is gone…

Johnny Nash…

I can see clearly now…

2016-09-20