Leadership SOS™
Turning Failure into Success

Presented by: Steve Greer

GMP Consultant, Leadership Coach, Keynote Speaker and Co-owner at Genesis Assist

genesis ASSIST℠ Coaching & Consulting

Introduction

Steve A. Greer

Consultant, Leadership Coach, & Speaker

Recent “Graduate” of Procter & Gamble QA External Engagement Leader

genesis ASSIST SM
Coaching & Consulting

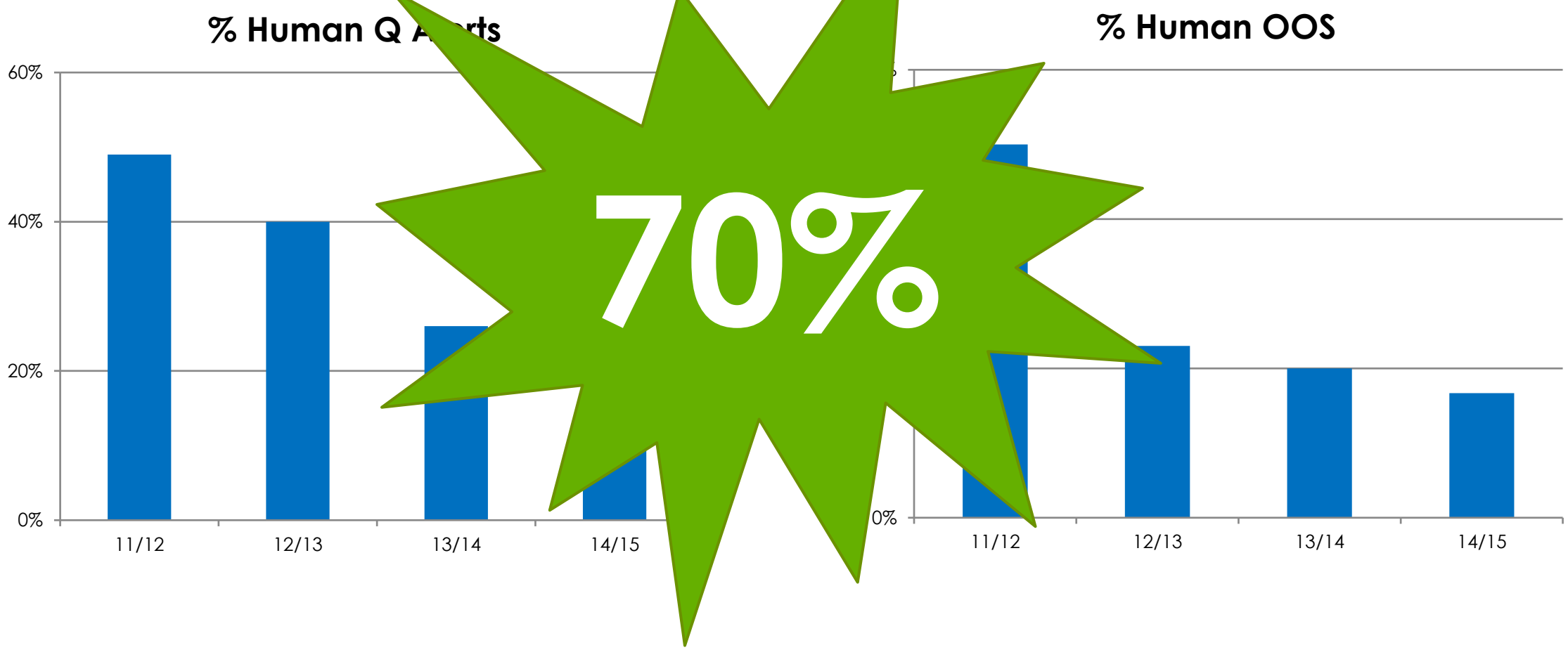
Leadership SOS™
Turning Failure into Success

Success = Ownership + Systems

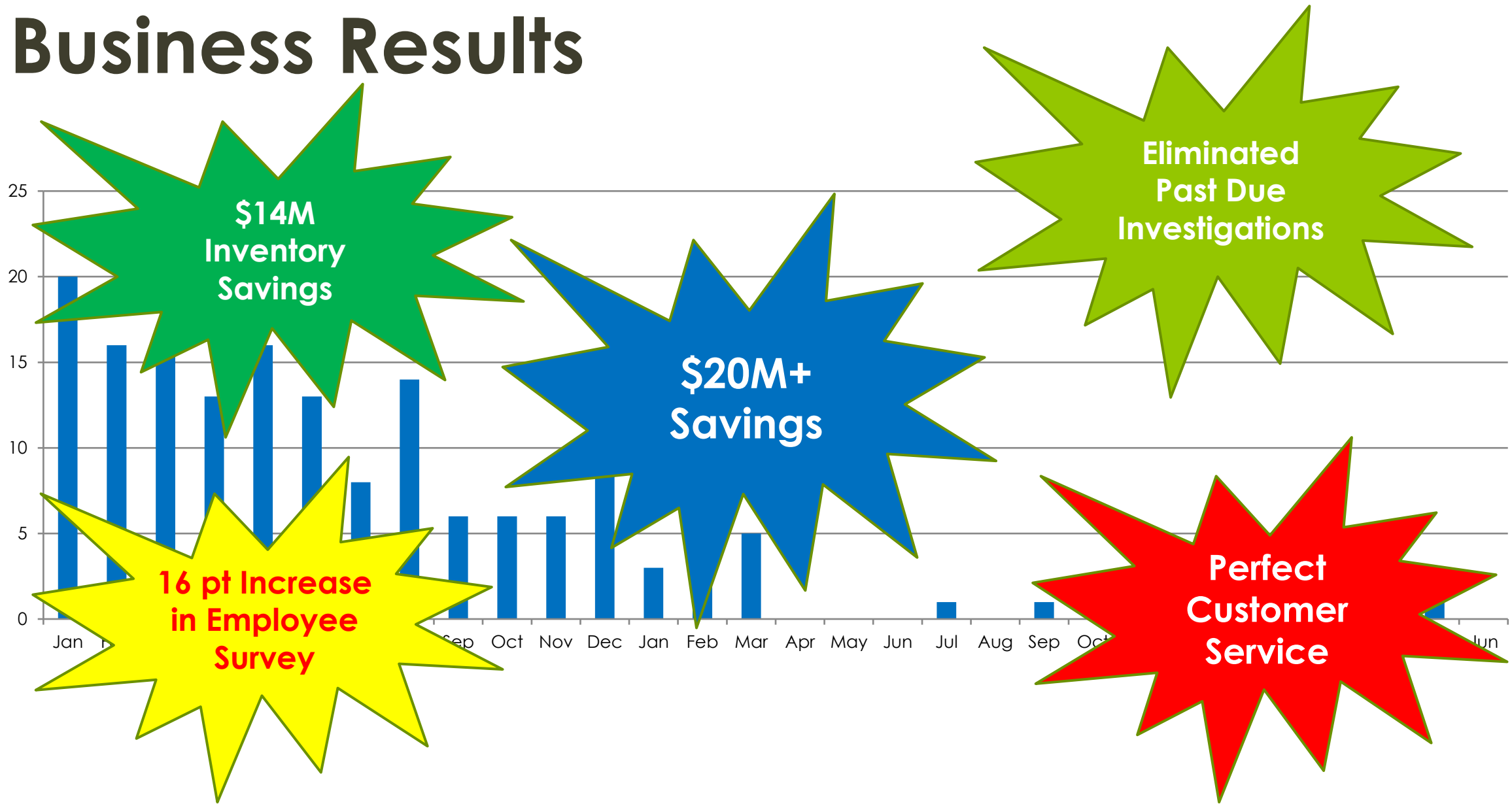

P&G
OLAY LLC
CAYEY PLANT

- Cost: $500K+/mo
- Service: 5% Missed
- Moral: ?

Human Alerts and OOS



Business Results




FDA Quality Metrics


Next Stop
Quality Management Maturity


Quality Management Maturity
Quality Metrics
Business Continuity
Enhanced Pharmaceutical Quality System
Communication and Collaboration
Sustainable Compliance
Quality Culture
Leadership Commitment to Quality
Customer Experience
Manufacturing Strategy and Operations
Employee Ownership and Engagement
Advanced Analytics
Risk Management
Continual Improvement
Productivity Optimization (5S)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Employee Ownership and Engagement
Advanced Analytics
Risk Management
Continual Improvement
Productivity Optimization (5S)

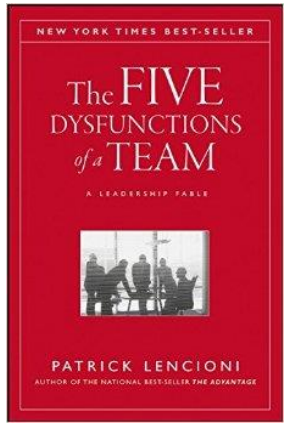
3 Guaranteed Ways to Fail


REFORM

Quality Our Consumers, Customers, Regulators and **Employees** trust everywhere, every time.

P&G Quality Promise

Effective Leadership



Success = **Ownership** + Systems

5,374

"THE IVORY" is a Laundry Soap, with all the fine qualities of a choice Toilet Soap, and is 99 44-100 **per cent. pure.**

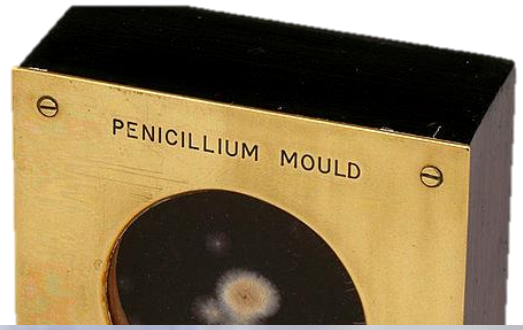
Ladies will find this Soap especially adapted for washing laces, infants' clothing, silk hose, cleaning gloves and all articles of fine texture and delicate color, and for the varied uses about the house that daily arise, requiring the use of soap that is above the ordinary in quality.

For the Bath, Toilet, or Nursery it is preferred to most of the Soaps sold for toilet use, being purer and much more pleasant and effective and possessing all the desirable properties of the finest unadulterated White Castile Soaps. The Ivory Soap will **"float."**

The cakes are so shaped that they may be used entire for general purposes or divided with a stout thread (as illustrated) into two perfectly formed cakes, of convenient size for toilet use.

The price, compared to the quality and the size of the cakes, makes it the cheapest Soap for everybody for every want. TRY IT.

SOLD EVERYWHERE.



To make a mistake is human, but to blame it on someone else, that's even more human.

Factory Mix-Up Ruins Up to 15 Million Vaccine Doses From Johnson & Johnson

A manufacturing subcontractor in Baltimore mixed ingredients from the coronavirus vaccines of Johnson & Johnson and AstraZeneca, delaying U.S. shipments of the "one-and-done" shot.

The New York Times

"In late February, one or more workers somehow confused the two during the production process, raising questions about training and supervision."

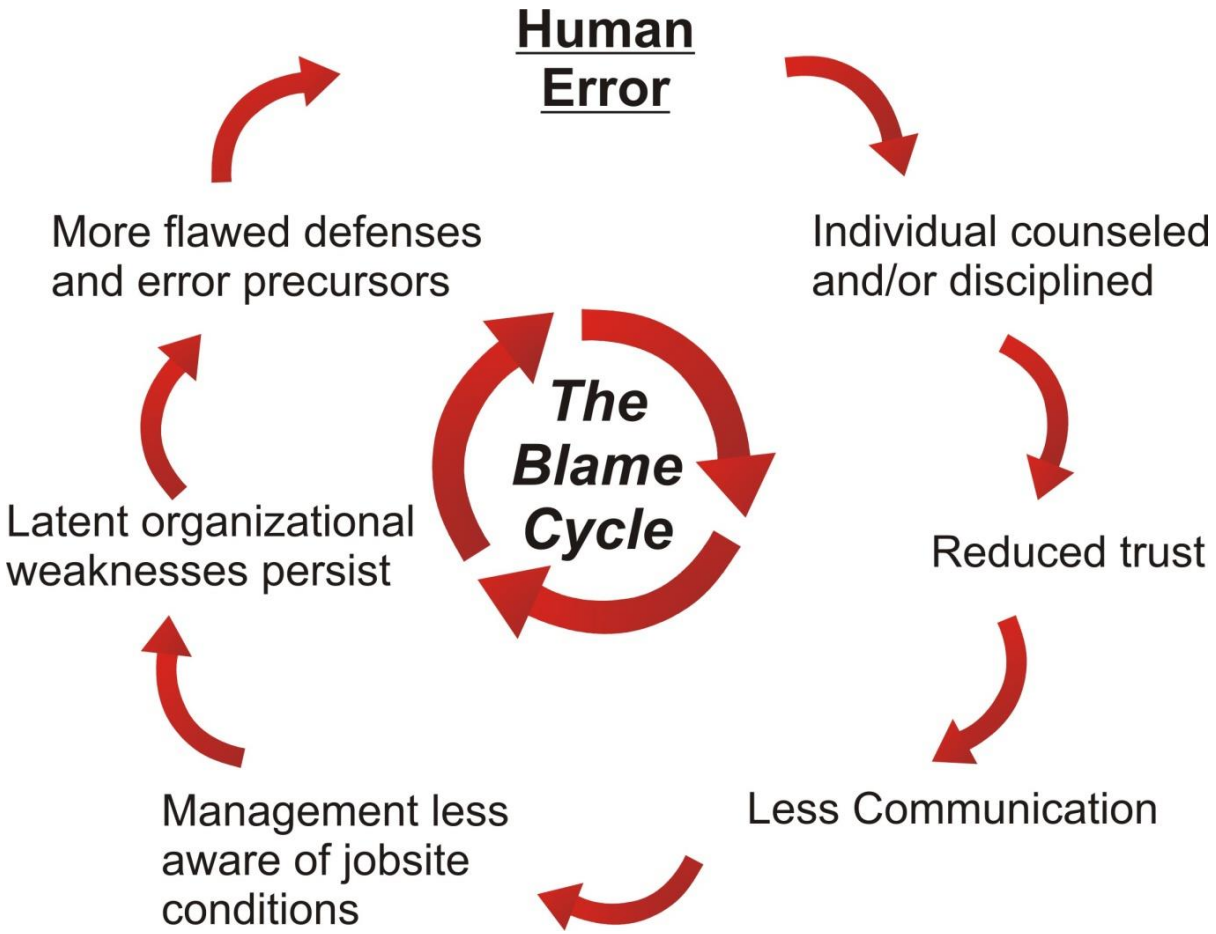
Observation 7 FDA 483 4/20/2021

Employees were not trained in the particular operation that they performed and/or in CGMPs related to their job function.

Specifically,

The firm has failed to adequately train personnel involved in manufacturing operations, quality control sampling, weigh and dispense, and engineering operations to prevent cross contamination of bulk drug substances created for client (b) (4) and client (b) (4).

Blame Cycle



Source: Ginette Collazo

Change Our Questions to Change Our Destiny

Whose Fault is it?

Change Our Questions to Change Our Destiny

What Can I do

Differently?

Success = Ownership + **Systems**

96%

“A bad system will beat a good person every time”

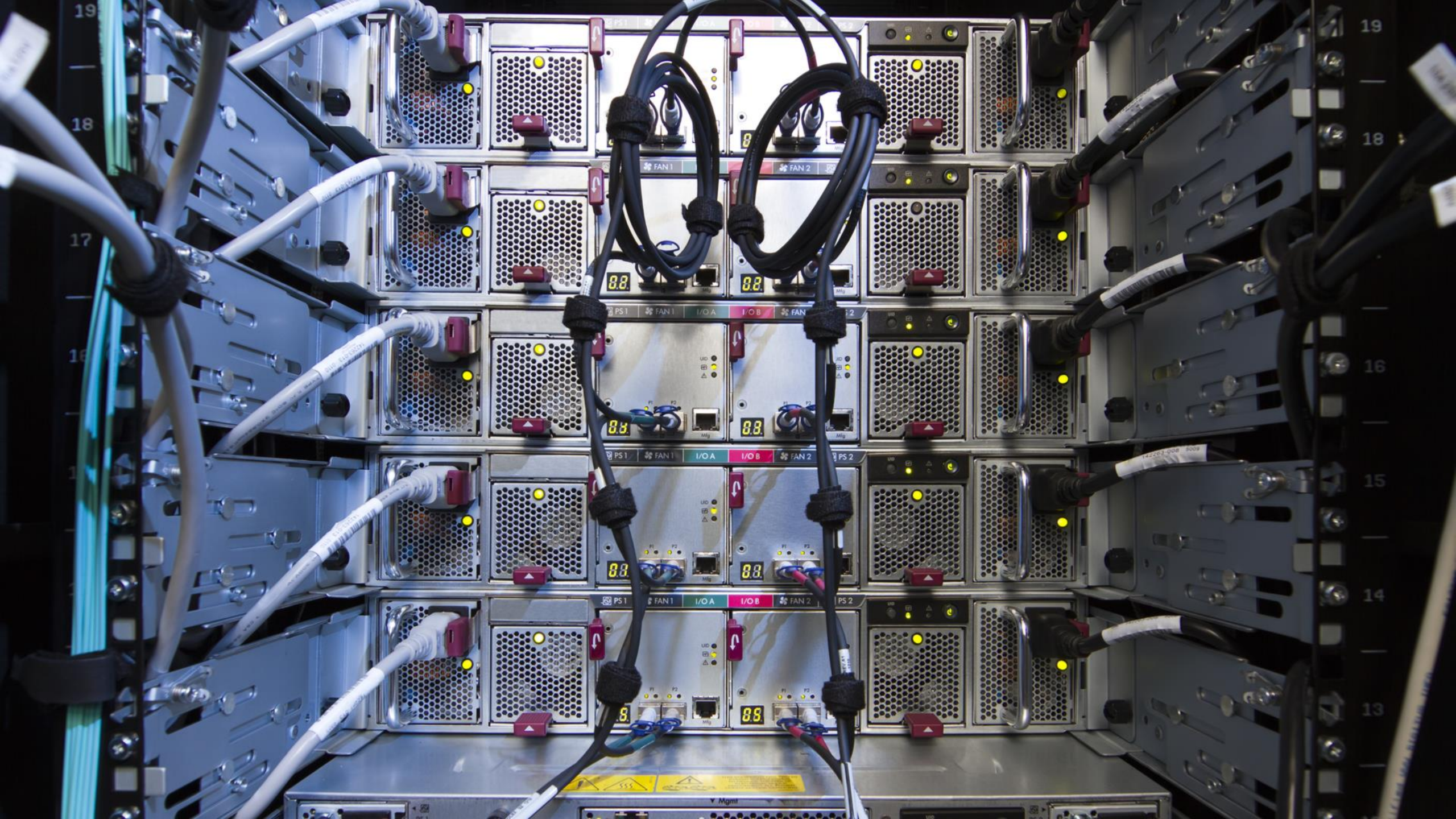
W. Edwards Deming

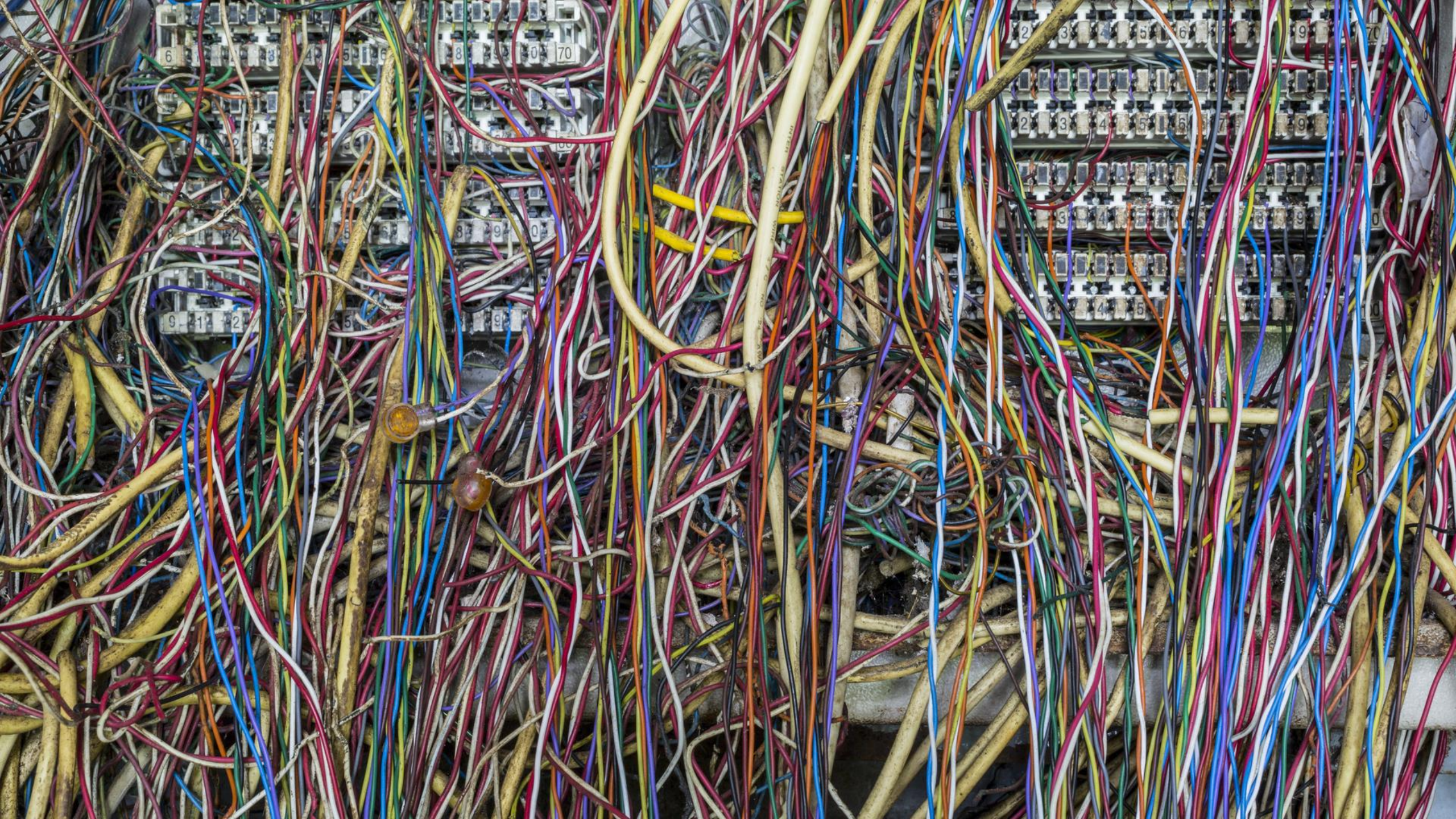
Human Error Rate

▪ Read a single number wrong	2	10,000
▪ **Read a clear 5 letter word wrong**	3	10,000
▪ Read a checklist wrong	1	1,000
▪ Perform the wrong visual inspection	3	1,000
▪ Record information wrong	1	100
▪ **Read an unclear 5 letter word wrong**	3	100
▪ Fail to notice wrong position of valves	5	10
▪ Fail to act after 1 min in emergency	9	10

Dr. David J. Smith, "Reliability and Maintainability and Risk"

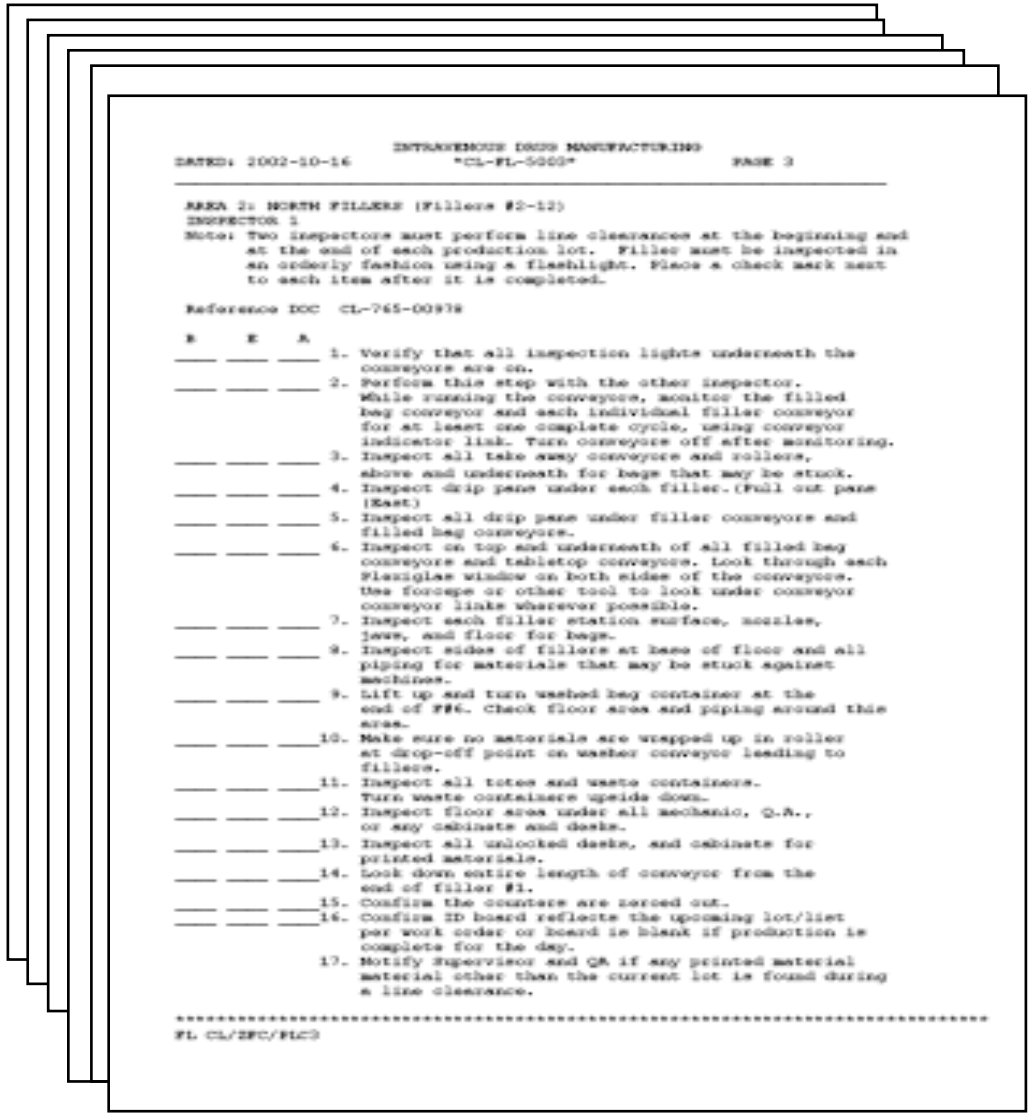

simplify


FAN 1
FAN 2
PS 1
I/O A
I/O B
PS 2
Mgmt



Procedures are the single leading cause of confusion

Are Your SOPs "Complete" or Easy to Apply?



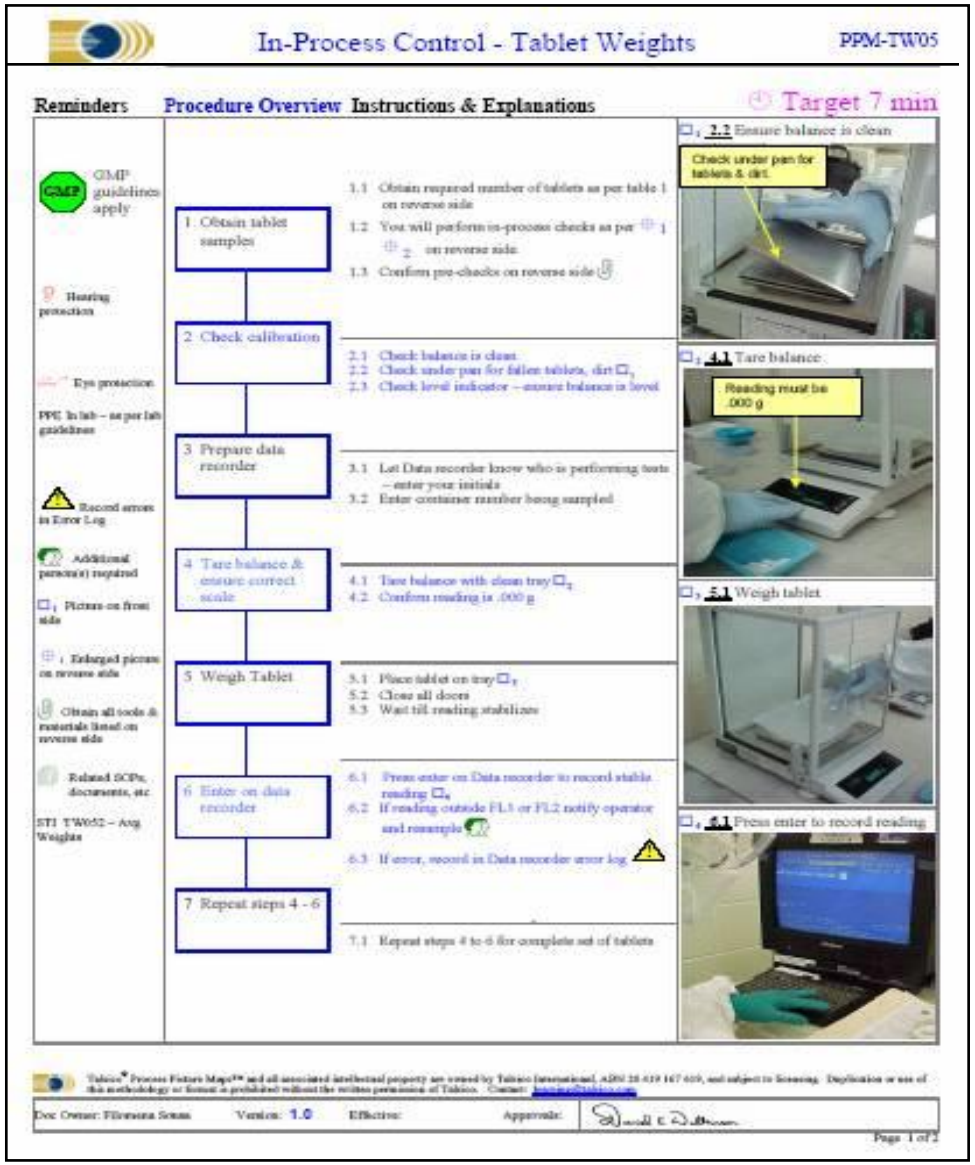
INTRAVENOUS DRUGS MANUFACTURING
DATED: 2002-10-16 "CL-FL-5000" PAGE 3

AREA 2: NORTH FILLERS (Fillers #2-12)
INSPECTOR 1
Note: Two inspectors must perform line clearances at the beginning and at the end of each production lot. Filler must be inspected in an orderly fashion using a flashlight. Place a check mark next to each item after it is completed.

Reference DOC CL-765-00978

B	E	A	
____	____	____	1. Verify that all inspection lights underneath the conveyors are on.
____	____	____	2. Perform this step with the other inspector. While running the conveyors, monitor the filled bag conveyor and each individual filler conveyor for at least one complete cycle, using conveyor indicator link. Turn conveyors off after monitoring.
____	____	____	3. Inspect all take away conveyors and rollers, above and underneath for bags that may be stuck.
____	____	____	4. Inspect drip pans under each filler. (Pull out pans (East)
____	____	____	5. Inspect all drip pans under filler conveyors and filled bag conveyors.
____	____	____	6. Inspect on top and underneath of all filled bag conveyors and tabletop conveyors. Look through each Plexiglas window on both sides of the conveyors. Use forcepe or other tool to look under conveyor conveyor links wherever possible.
____	____	____	7. Inspect each filler station surface, nozzles, jaws, and floor for bags.
____	____	____	8. Inspect sides of fillers at base of floor and all piping for materials that may be stuck against machines.
____	____	____	9. Lift up and turn washed bag container at the end of FF6. Check floor area and piping around this area.
____	____	____	10. Make sure no materials are wrapped up in roller at drop-off point on washer conveyor leading to fillers.
____	____	____	11. Inspect all totes and waste containers. Turn waste containers upside down.
____	____	____	12. Inspect floor area under all mechanic, Q.A., or any cabinets and desks.
____	____	____	13. Inspect all unlocked desks, and cabinets for printed materials.
____	____	____	14. Look down entire length of conveyor from the end of filler #1.
____	____	____	15. Confirm the counters are zeroed out.
____	____	____	16. Confirm ID board reflects the upcoming lot/list per work order or board is blank if production is complete for the day.
			17. Notify Supervisor and QA if any printed material material other than the current lot is found during a line clearance.

FL CL/ZFC/FLC3



In-Process Control - Tablet Weights PPM-TW05

Reminders | Procedure Overview | Instructions & Explanations | Target 7 min

GMP guidelines apply
Hearing protection
Eye protection
PPE in lab – as per lab guidelines
Record errors in Error Log
Additional person(s) required
Picture on front side
Enlarged picture on reverse side
Obtain all tools & materials listed on reverse side
Related SOPs, documents, etc
STI TW052 – Avg Weights

1 Obtain tablet samples
1.1 Obtain required number of tablets as per table 1 on reverse side
1.2 You will perform in-process checks as per 1 2 on reverse side
1.3 Confirm pre-checks on reverse side

2 Check calibration
2.1 Check balance is clean
2.2 Check under pan for fallen tablets, dirt
2.3 Check level indicator – ensure balance is level

3 Prepare data recorder
3.1 Let Data recorder know who is performing tests – enter your initials
3.2 Enter container number being sampled

4 Tare balance & ensure correct scale
4.1 Tare balance with clean tray
4.2 Confirm reading is .000 g

5 Weigh Tablet
5.1 Place tablet on tray
5.2 Close all doors
5.3 Wait till reading stabilizes

6 Enter on data recorder
6.1 Press enter on Data recorder to record stable reading
6.2 If reading outside FL3 or FL2 notify operator and resample
6.3 If error, record in Data recorder error log

7 Repeat steps 4 - 6
7.1 Repeat steps 4 to 6 for complete set of tablets

2.2 Ensure balance is clean
Check under pan for tablets & dirt

4.1 Tare balance
Reading must be .000 g

5.1 Weigh tablet

6.1 Press enter to record reading

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Doc Owner: Filomena Sousa Version: 1.0 Effective: Approvals:

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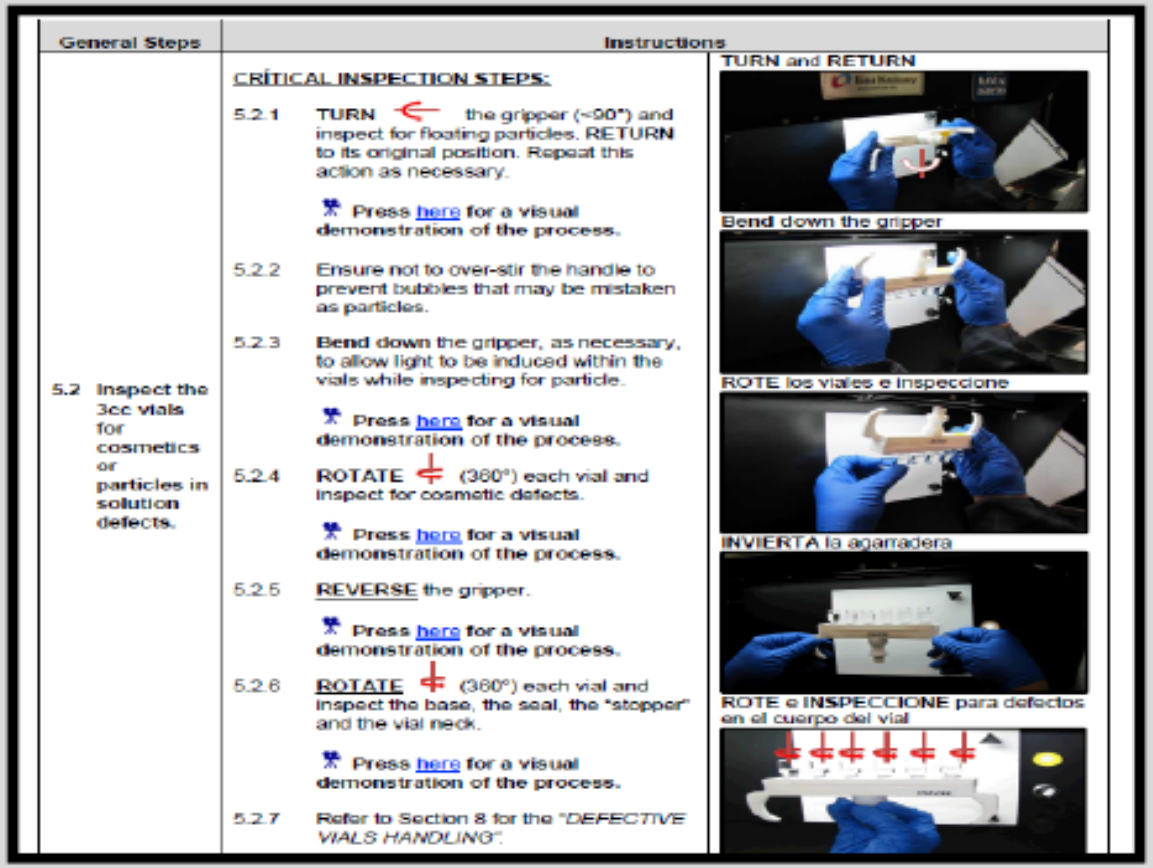
Source: Talsico International

SOPs Reinvented

- **Seeing a video demonstration real-time will:**
  - ✓ **Reduce Training Time**
  - ✓ **Improve Understanding of Step to be Performed**
  - ✓ **Reduce Non-Conformances**
  - ✓ **Increase Adherence to Procedure**
  - ✓ **Allow for SOP Simplification**
  - ✓ **Increase ability to consistently supply patients**



General Steps	Instructions
5.2 Inspect the 3cc vials for cosmetics or particles in solution defects.	CRITICAL INSPECTION STEPS: 5.2.1 TURN ← the gripper (~90°) and inspect for floating particles. RETURN to its original position. Repeat this action as necessary. Press here for a visual demonstration of the process. 5.2.2 Ensure not to over-stir the handle to prevent bubbles that may be mistaken as particles. 5.2.3 Bend down the gripper, as necessary, to allow light to be induced within the vials while inspecting for particle. Press here for a visual demonstration of the process. 5.2.4 ROTATE ↓ (360°) each vial and inspect for cosmetic defects. Press here for a visual demonstration of the process. 5.2.5 REVERSE the gripper. Press here for a visual demonstration of the process. 5.2.6 ROTATE ↓ (360°) each vial and inspect the base, the seal, the "stopper" and the vial neck. Press here for a visual demonstration of the process. 5.2.7 Refer to Section 8 for the "*DEFECTIVE VIALS HANDLING*".

User focuses on flawless execution instead of SOP interpretation

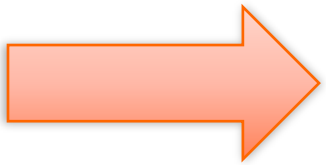
Checklists

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

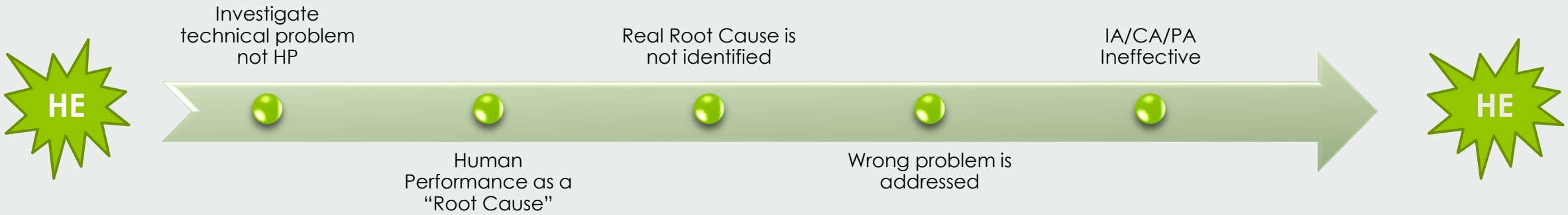
A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

GEMBA – Leaders on the Floor



Solving the Wrong Problem

Investigate Human Performance Differently



5 ERRORS

Root cause analysis for human error events rarely gets to the real issues.

Ginette Collazo

Root Cause

The most basic cause (or causes)

that can reasonably be identified

that **leadership has control to fix**

and, when fixed, will prevent

(or significantly reduce the likelihood of)

the problem's recurrence.

Adapted from Mark Paradies,
System Improvements

Root Cause Determination Tool™

Human Performance Event

Procedure

Procedure Not Used
- Not Available
- Inconvenient to Obtain
- Difficult to Use
- Use Needs to be Required
- No Task Procedure

Misleading or Confusing
- Format
- Multiple Actions per Step
- Needs Check Off Space
- Inadequate Checklist
- Graphics
- Ambiguous Instructions or Requirements
- Level of Detail
- Excessive References
- Insufficient Resources

Wrong or Incomplete
- Typographical Error
- Sequence Wrong
- Facts Wrong or Incorrect Requirements
- Incorrect Revision
- Requirements Inconsistency
- Incomplete or Situation Not Covered
- Data/Computations Wrong or Incomplete
- Overlap or Gaps Between Procedures

Training

No Training
- Decision Not to train
- Training Requirements Not Identified

Training Records System
- Training Records Incorrect
- Training Records Not Up-to-Date

Training
- Job/Task Analysis
- Program Design
- Training Objectives
- Lesson Content
- On the Job Training
- Qualification Testing
- Continuing Training
- Training Support
- Equipment
- Instructor Qualifications
- Training Methods
- Abnormal Events or Emergency Training
- Qualifications Standard

Communication

Lack of or Untimely
- Method Not Available
- Communication Between Work groups
- Communication Between Shift Workers and Management
- Communication with Contractors
- Communication with Customers

Misunderstood
- Standard Terminology Not Used
- Unused Verification or Repeat-back
- Long Message
- Speech Interference
- Wrong Instructions

Work Shift Turnover
- Communication Within Shifts
- Communication Between Shifts

Engineering

Workplace Layout
- Controls or Displays
- Control or Display Location
- Control or Display Integration
- Conflicting Layouts
- Reach or Visual Envelope
- Labeling

Work Environment
- Housekeeping
- Climate
- Lighting
- Excessive Noise
- Clothing/PPE
- Other Environmental Stressors
- Tools

Workload
- Knowledge-based Decision Required
- Excessive Control Action Required
- Unrealistic Monitoring Required
- Excessive Mental Math, Memory, Logic Required

Intolerant System
- Errors Not Detectable
- Errors Not Recoverable

Immediate Supervision

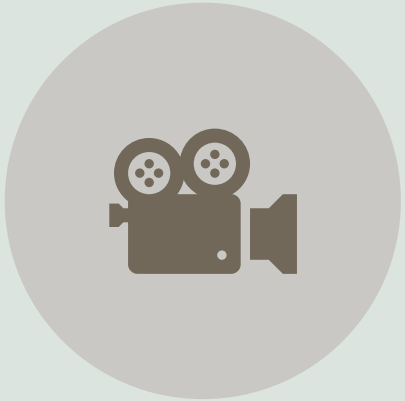
Preparation
- No Preparation
- Job Plan
- Instruction to Workers
- Walkthrough
- Scheduling
- Worker Selection or Assignment

Work Supervision
- No Supervision
- Supervision
- Improper Performance Not Corrected
- Teamwork

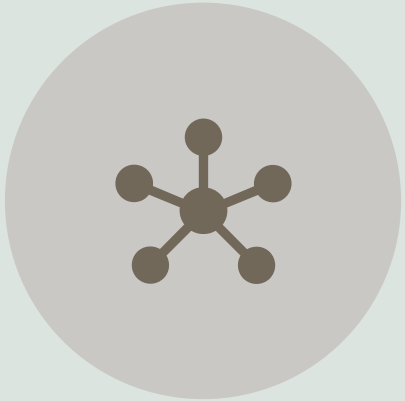
Individual Performance

- Slip Lapse (unintentional action; memory and attention failures)
- Mistake (intentional; failure in judgment or interferential process). No harm intended
- Violation (repeated event or known consequences)

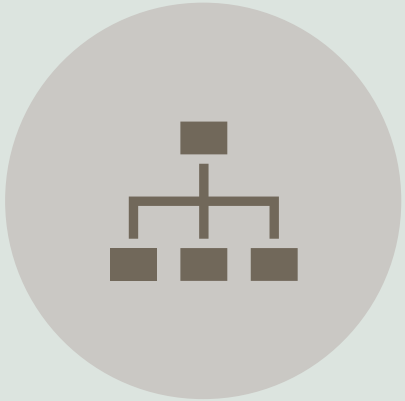
Human Memory Considerations



NOT A MOVIE



HIGHLY COMPLEX, INTERCONNECTED



TEND TO ORDER AND STRUCTURE EVENTS

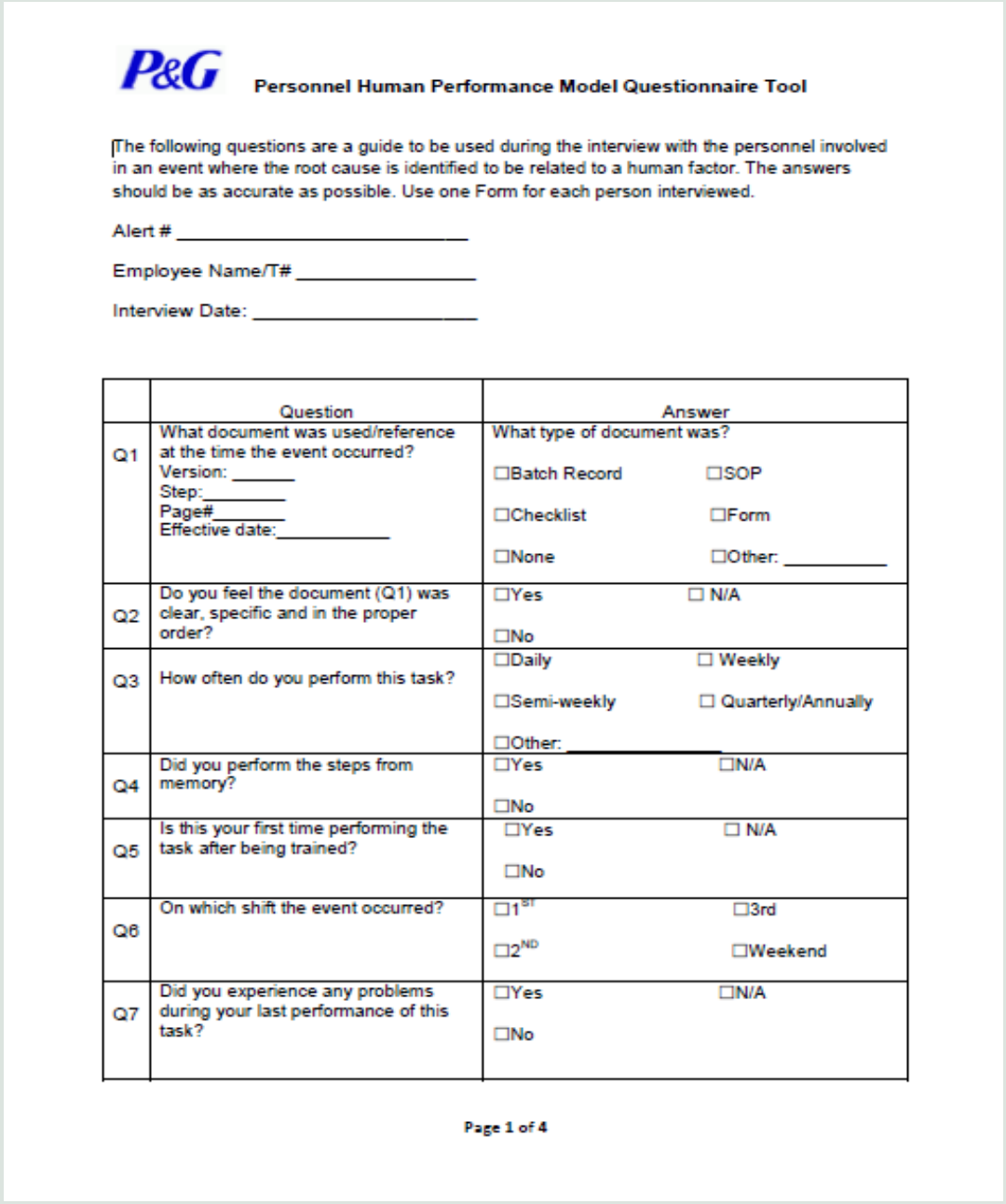
Adapted from Ginette Collazo

Interviews

Interviews are not about asking questions …

they are about **stimulating memories**

Mark Paradies, System Improvements



P&G

Personnel Human Performance Model Questionnaire Tool

The following questions are a guide to be used during the interview with the personnel involved in an event where the root cause is identified to be related to a human factor. The answers should be as accurate as possible. Use one Form for each person interviewed.

Alert # _____

Employee Name/T# _____

Interview Date: _____

	Question	Answer
Q1	What document was used/reference at the time the event occurred? Version: _____ Step: _____ Page# _____ Effective date: _____	What type of document was? ☐Batch Record ☐SOP ☐Checklist ☐Form ☐None ☐Other: _____
Q2	Do you feel the document (Q1) was clear, specific and in the proper order?	☐Yes ☐ N/A ☐No
Q3	How often do you perform this task?	☐Daily ☐ Weekly ☐Semi-weekly ☐ Quarterly/Annually ☐Other: _____
Q4	Did you perform the steps from memory?	☐Yes ☐N/A ☐No
Q5	Is this your first time performing the task after being trained?	☐Yes ☐ N/A ☐No
Q6	On which shift the event occurred?	☐1ST ☐3rd ☐2ND ☐Weekend
Q7	Did you experience any problems during your last performance of this task?	☐Yes ☐N/A ☐No

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TAKE ACTION

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