DEFINING QUALITY CULTURE, KEY PRINCIPLES AND LEADERSHIP'S ROLE

Judy Morgan
VP, Chief Compliance Officer
Pace© Corporate HQ
Judy.morgan@pacelabs.com

AGENDA

DISCUSSION POINTS:

1. Quality Failure: How did it happen?
2. What is Quality? Quality Assurance? Quality Management? Quality Culture?
3. Balancing the responsibilities between the right leaders
4. Prioritizing the tasks
5. Accountability
6. The foundation and principals of a quality culture

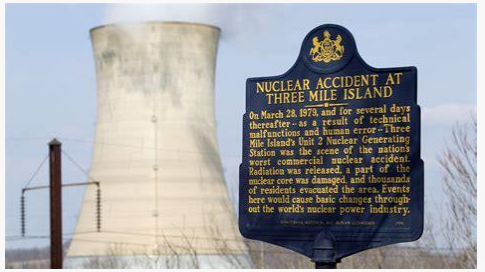
QUALITY FAILURE LEADS TO WORST NUCLEAR DISASTER IN U.S. HISTORY

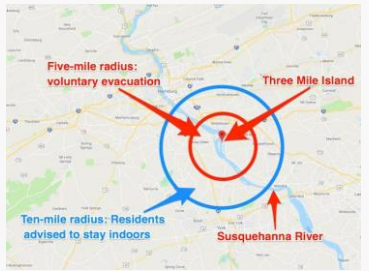
THREE MILE ISLAND

DATE: March 28, 1979

WHAT WENT WRONG:

- Failure to have the proper process in place to indicate if systems were working correctly
- No secondary indicator systems to verify the primary control = No checks & balances
- Main system indicated feedwater pumps had tripped but no indicator to warn no cooling water was flowing due to a closed block valve in feedwater lines
- Closing block valves without shutting down the reactor is a major NRC violation





QUALITY FAILURE CAUSED TIRE MALFUNCTIONS IN FORD EXPLORER IN 2000s

TIRE MALFUNCTIONS DUE TO TREAD SEPARATION CAUSED BLOWOUTS RESULTING IN CRASHES KILLING 300 PEOPLE

WHAT WENT WRONG:

- Explorer had higher tendency to flip over in sharp turns, but underinflating the tires reduced the problem significantly (26psi vs the tire mfg of 35psi)
- Underinflated tires creates more road friction thus generating higher heat in the tire causing tread separation
- The tire specification also allowed for the less heat resistant C grade tire rather than the more heat resistant B grade tire. ($$$$ savings to Ford)
- They did find a design flaw in the ATX tire model that contributed, but was not the sole cause.

QUALITY

- The degree of excellence or the inherent characteristics of something that determines its ability to satisfy needs or expectations.
- How good or bad something is, often relating to its performance, durability, and overall value.

WHAT IS QUALITY ASSURANCE?

- The systematic efforts taken to assure that the product delivered to customer meet with the contractual and other agreed upon performance, design, reliability, and maintainability expectations of that customer in manufacturing and service industries
- The core purpose is to **prevent mistakes and defects** in the **development and production** of both manufactured products and delivered services

QUALITY MANAGEMENT

- The process of overseeing all activities and tasks needed to maintain a desired level of excellence in products and services.
- Achieved through quality planning, quality assurance, quality control, and quality improvement to ensure customer satisfaction and loyalty.
- A quality management system is only as effective as **management's dedication and insistence** to adherence and accountability.
- Just checking the boxes with current documentation and audit schedules is not enough.
- The system is only as effective as the collective people in the organization and how the business inspires, empowers, leads and supports employees as they take responsibility for the system's operation and results.

QUALITY CULTURE

Quality culture is the collective commitment of every individual in an organization to do the right thing, the right way, every time—even when no one is watching. It's the invisible force that determines:

"A true quality culture exists when **doing things right becomes second nature**—woven into daily behavior, not driven by checklists or fear of audits."

How people **approach their work**

How they **respond to problems**

How deeply they care about **customer outcomes, compliance, and continuous improvement**

WEAK QUALITY CULTURE

- Blaming individuals instead of fixing systems
- Hiding problems out of fear
- Prioritizing output over compliance
- Treating QA as a policing function
- Addressing symptoms rather than causes
- Rewarding speed more than accuracy

PRINCIPLES OF QUALITY CULTURE

DO THE RIGHT THING ALWAYS

Integrity matters…even when no one is watching.

SPEAK UP WITHOUT FEAR

Issues, risks, and ideas for improvement are welcomed and acted on.

QUALITY IS EVERYONE'S JOB

From lab tech to leadership, everyone contributes to quality outcomes.

FIX SYSTEMS, NOT JUST PEOPLE

Focus is on improving processes, not blaming individuals.

LEARN AND IMPROVE CONTINUOUSLY

Mistakes are seen as learning opportunities, not failures to hide.

CUSTOMER AND COMPLIANCE FOCUSED

Every decision considers the end user and regulatory expectations.

WHO IS RESPONSIBLE FOR QUALITY?

Standard answer = EVERYONE

Is it really that simple?

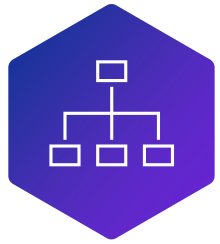
RACI CHART: Responsible (performs the task), Accountable (ultimately answerable), Consulted (provides insight and input), and Informed (kept up to date)

ACTIVITY	EMPLOYEES	SUPERVISORS / MANAGERS	PROCESS OWNERS/ TECHNICAL	QUALITY TEAM	SENIOR MANAGEMENT
Detect quality issue	R	**A**	C	C	I
Initiate deviation or non-conformance report	R	**A**	C	C	I
Conduct root cause investigation	C	R	R	**A**	I
Develop corrective action	C	R	**A**	C	I
Implement corrective action	R	**A**	**A**	C	I
Verify effectiveness of action	C	C	C	**A**	I
Ensure timely closure	C	C	C	**A**	**A**
Report trend/systemic issues		C	R	**A**	**A**
Communicate with regulators/customers				**A**	R

PRIORITIZE WITH PURPOSE: NON-CONFORMANCES & RELATED TASKS

USE A RISK-BASED CRITICALITY MATRIX

EVALUATE USING 3 FACTORS: IMPACT, FREQUENCY * DETECTABILITY



APPLY A SCORING OR TIERING TOOL

DOCUMENT CRITERIA CLEARLY IN SOPs

ESCALATE WHEN IN DOUBT

USE A RISK-BASED CRITICALITY MATRIX

Many organizations use a **3- or 4-tier system** such as: Critical / Major / Minor / Observation based on **impact and likelihood**

SEVERITY	DESCRIPTION	EXAMPLE
CRITICAL	Deviation poses immediate risk to data integrity, traceability, or regulatory compliance OR has direct impact on safety, public health, regulatory violation	Release of wrong or invalid data, falsified data/records, Invalid calibration, analysis without required method validation, missed holding times.
MAJOR	May impact product quality or compliance; no direct safety issue	Incomplete batch records, missed calibration, use of expired standards, incomplete method SOP, uncontrolled document revisions.
MINOR	Low risk to product quality or compliance; usually procedural or documentation	Typos, missing initials, unsigned training log, control charts not updated, isolated logbook oversight.
OBSERVATION	Improvement area or low-risk process inefficiency without compliance violation. Not a deviation yet, but could become one; good for continuous improvement	Poor housekeeping, unclear SOP wording, typo

EVALUATE USING 3 FACTORS

Combine these to assign risk priority—similar to **FMEA (Failure Modes and Effects Analysis)** logic.

✅ A) IMPACT (SEVERITY)

Will this affect **product safety**, **efficacy**, or **compliance**?

Could it lead to a **regulatory finding** or **customer complaint**?

✅ B) LIKELIHOOD (PROBABILITY)

Has this happened before? How often?

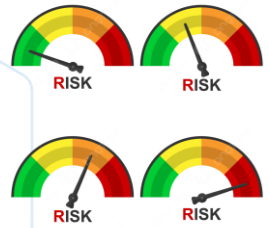
Is it a **one-off** or part of a **trend**?

✅ C) DETECTABILITY

Was it caught by routine controls or **after release**?

Could it go **undetected** in the future?

APPLY A SCORING OR TIERING TOOL



You can use a simple Risk Priority Number (RPN) formula:

RPN = Severity × Likelihood × Detectability **OR** assign categories like:

SCORE / TIER/ RPN RANGE	EXAMPLE	ACTION REQUIRED
High (Critical) 80 - 125	Does the issue violate TNI or ISO 17025 requirements that directly affect result validity or regulatory obligations?	Immediate containment, investigation, report to leadership/regulators
Medium (Major) 41 - 80	Is the issue systemic or could it affect reproducibility, traceability, or impartiality of results?	Timely investigation and CAPA
Low (Minor) 16 - 40	Is the issue procedural/documentary with no material impact on quality system outputs?	Document and monitor, fix as needed
Informational 1 - 15	Does the issue warrant preventive attention or continuous improvement?	Track for trends; not requiring action

DOCUMENT CRITERIA CLEARLY IN SOPs

The internal quality SOP should:

- Define what qualifies as each tier – consistent classification of issues
- Include examples
- Assign timelines and escalation requirements based on priority
- Define who assigns criticality (e.g., QA staff)

ESCALATE WHEN IN DOUBT

1. If the impact of failure isn't clear, or there's cross-functional risk, default to escalation and involve the bigger team via cross-functional assessment.
2. Better to reclassify later than under-prioritize upfront.
3. Be prepared! Establish a known escalation path for issues.

WHY ACCOUNTABILITY MATTERS

Accountability is the anchor of an effective quality system. Without clear ownership:

- Problems get passed around instead of solved
- Corrective actions stall or stay superficial.
- Compliance risk increases due to inaction.
- Morale suffers as responsible individuals are either unfairly blamed or not empowered.

WHAT IS CLEAR OWNERSHIP?

- Ensures timely action and resolution
- Prevents recurrence by addressing root causes
- Avoids blame culture and builds team trust
- Supports compliance and continuous improvement

ACCOUNTABILITY VS OWNERSHIP

ACCOUNTABILITY:

The person or role ultimately answerable for the outcome—regardless of who does the work.

OWNERSHIP:

The role responsible for resolving an issue, improving a process, or fixing a deviation.

✅ Every step in a quality process must have a clear "owner" who drives it forward and an "accountable" person who ensures it gets done right.

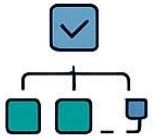
PRINCIPLES FOR ASSIGNING ACCOUNTABILITY

1. Tie Accountability to Process Ownership
    - Assign accountability to the function that controls the process where the failure occurred—not just QA or a manager by default.
        - Example: A lab analyst skips a control check — the Lab Supervisor is accountable for oversight, training, and reinforcement.
2. Keep QA as the Oversight Function, Not the Catch-All
    - QA ensures that accountability is correctly assigned and timelines are met.
    - QA should not absorb operational failures or be required to fix them.
3. Ensure Role-Based Involvement Across the Lifecycle (Follow RACI Chart)
4. Make It Visible and Trackable (Track response time, completion rate, by role, by issue etc. and escalate where necessary)

YOU CAN'T JUST THROW IT OVER THE FENCE TO SOMEONE ELSE!

Foundations and Principles of Quality Culture

Foundations of Quality Oulture



- **Clear Accountability and Role Ownership**
  Every risk, deviation, and outcome has a defined owner RACI structures ensure no ambiguity.

- **Risk-Based Thinking.** Issues are prioritized based on severity, frequency. and detectability. Tools like RPN (Risk Priority Number) ensure consistency.

- **Integrated Compliance Framework** Quality is aligned with TNI NELAP, ISC/IEC 17025, and regulatory expectations'. Quality is not optional–it's embedded in how business is done.

- **Data-Driven Decision Making** Trends. metrics, audit findings, and deviations drive actions–not assumptions. Visibility of data empowers teams to act early.

- **Leadership Commitment and Modeling**
  Leaders demonstrate quality-first behavior.

Principles of Quality Culture

- **Do the Right Thing-Even When No One is Watching**
  Integrity is non-negotiable. Compliance isn't circumstantial.

- **Everyone Owns Quality** From entry-level staff to senior leadership, quality is everyone's job.
- **Fix Systems, Not Just People** Errors are seen as symptoms of process weakriess, not individual failure.

- **Speak Up Without Fear** Issues and risks are raised early. Psychological safety is protect:
- **Learn, Improve, and Prevent** Mnstakes become fuel for improvement, not punishment. Continuous improvement is ongoing–not a one-rime time initiative.

THANK YOU!

Judy Morgan

VP, Chief Compliance Officer

Judy.morgan@pacelabs.com

LET'S CONNECT
Scan QR code to
connect on LinkedIn