# MAINTAINING A QUALITY CULTURE - PERFORMANCE METRICS, BEST PRACTICES AND QMS ELEMENTS

Quality Culture a Foundational Driver of Data Quality, Improvement and Operational Excellence in the Laboratory

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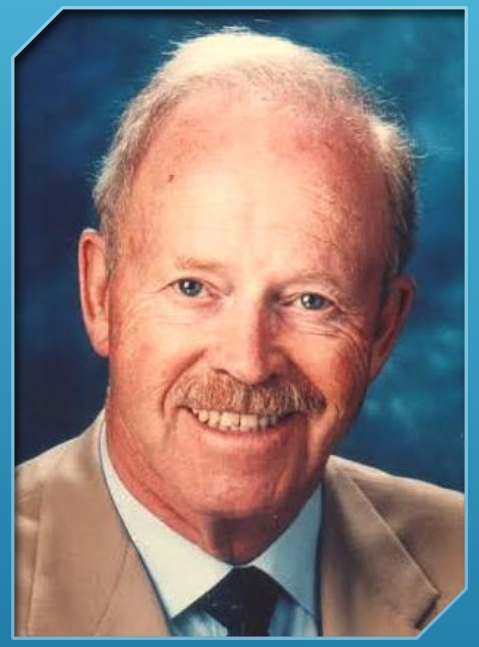
# OBJECTIVES OF THE PRESENTATION

- Understand today's thinking on metrics for a laboratory's quality culture.
- Explore some best practices to enhance a quality culture.
- Discuss processes within a quality management system (QMS) that support the quality culture.

# PHILIP CROSBY:



"Quality is the result of a carefully crafted cultural environment. It has to be the fabric of the organization, not part of the fabric."

Crosby's insight drives home the point that quality isn't an add on, it must be woven into **every aspect** of a company's identity and operations. That is a true quality culture.

- "I believe culture only exists when culture is defined in terms of "**actions.**" Its all about actions. Actions demonstrate the culture. With no defined actions, the culture can be just words. For example, are we to say a good quality culture means there is "management support." Then what actions constitute management support or leadership support? Funding the quality work? Ensuring corrective actions are followed up on? What is a quality culture mindset? What actions demonstrate that mindset?"

## JEFFERY WORTHINGTON

Former:

Director of Quality

USEPA OEI

# So how might you envision or define quality culture in a laboratory setting.

- Quality culture is more about **mindset, values, and behaviors** within an organization. That is, having everyone the same fundamental mindset and being on the same page when it comes to quality!
- With the above, in mind, be on the lookout for red flags and early warnings signs that your quality culture is weak.


Some Red Flags of a Weak Quality Culture:

- Transparency gets punished
- QA is seen as "compliance police"
- Risk are downplayed to meet TAT or OTD
- Prevention and Continuous Improvement are deprioritized (reactive verse proactive)
- People stay silent to "not rock the boat" or stay out of trouble with upper management
- Silo mentality
- Low accountability
- Lack of leadership engagement

**What can be done to help maintain a quality culture?**

## WARNING SIGNS

Ignore them, and the cost is strategic, reputational, regulatory and ultimately, it puts the organization, clients, environmental protection and public health at risk!

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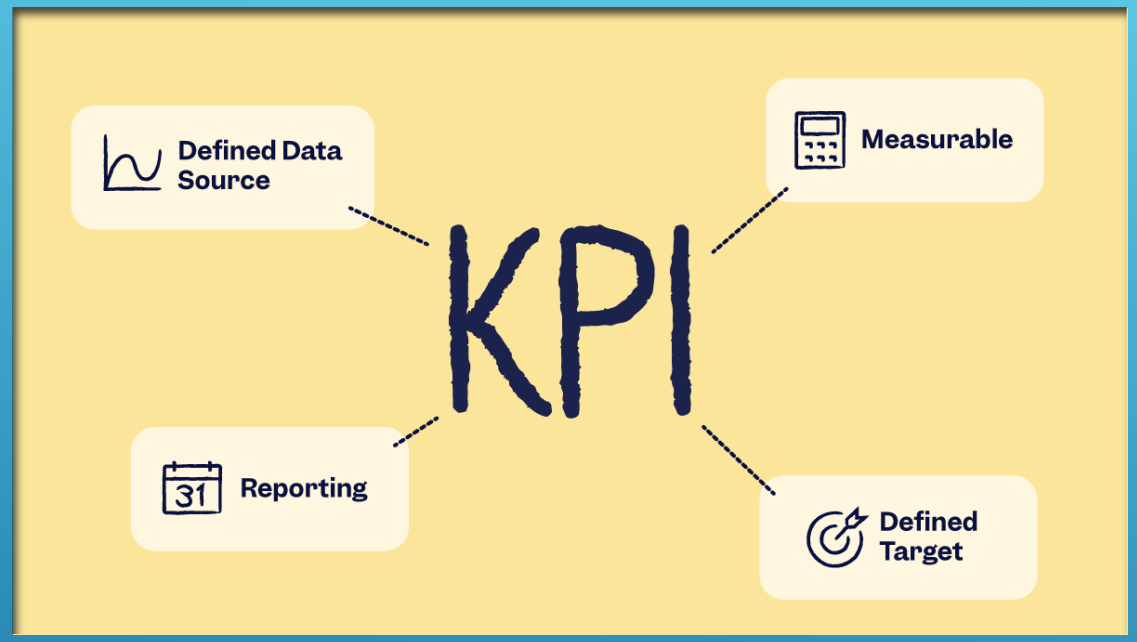
# MAINTAINING THE QUALITY CULTURE

However, while not explicitly stated in standards, many aspects of quality culture - such as leadership commitment, staff competence, and continuous improvement - are **implicitly supported and maintained** through use of:

**performance metrics,**

**best practices,**

**quality management system**




- List traditional **"lagging"** metrics and describe **"leading"** metrics and their role as quality culture indicators.
- Need to blend leading and lagging metrics to manage better.

# ROLE OF PERFORMANCE METRICS IN A LABORATORY QUALITY CULTURE

- On Time Delivery.
- Revised Reports.
- Error and Defect Rates: Monitor and minimize mistakes.
- Compliance Metrics: Adherence to regulations and standards.
- Customer Complaints
- Audit Findings and Audit Closure
- SOP Reviews and Revisions
- Corrective Actions Completed
- Loss of Accreditation
- Etc. https://apps.nelac-institute.org/nemc/2021/docs/presentations/pdf/8-2-21-Best%20Management%20Practices%20for%20Environmental%20Laboratories-2.01-Siders.pdf

# TRADITIONAL (LAGGING) QUALITY AND CUSTOMER FOCUSED METRICS


# TODAY'S LEADING METRICS TO CONSIDER FOR QUALITY CULTURE

"KPIs: A New Approach" by Robertson Hunter Stewart is a great read on this. The key? Triangulating data - hard metrics + employee feedback + observed behaviors - to paint a complete picture of quality culture maturity. A people-first approach that measures transparency, motivation, and ownership alongside the numbers."

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# TODAY'S LEADING METRICS TO GAUGE AND SUSTAIN A QUALITY CULTURE

Examples of tools to use to measure this new approach to KPI's for a Quality Culture:

- Employee Satisfaction
- Engagement Survey (do employees feel connected)
- Employee Experience Survey
- Cost of Turnover (Employee Retention Rates)
- Percentage of Absenteeism
- Employee Needs Survey
- Employee Wellbeing

- **Employee Engagement & Empowerment:** Regular surveys, walk abouts, and feedback mechanisms that gauge commitment to quality values and the effectiveness of quality improvement initiatives. Are quality culture objectives truly woven into daily practices?
- **Proactive Risk Management:** Tracking early warning signs (for example, the frequency of trend analysis, risk assessment completions, and incident reporting) to identify when processes are deviating from QC criteria or best practices before they result in non-compliances.
- **Continuous Improvement Participation:** Metrics on how many process improvement suggestions are submitted, implemented, and their impact on workflow or product quality.

# TODAY'S LEADING METRICS TO GAUGE AND SUSTAIN A QUALITY CULTURE

- Cultural Surveys
- Leadership Behavior Observations (do they ‘walk the talk’)
- Leadership Communications (how often and effective)
- Peer Reviews to Capture Overall Climate
- Values Adherence by Management
- Team Collaboration (effectively work together and share quality insights across functions)

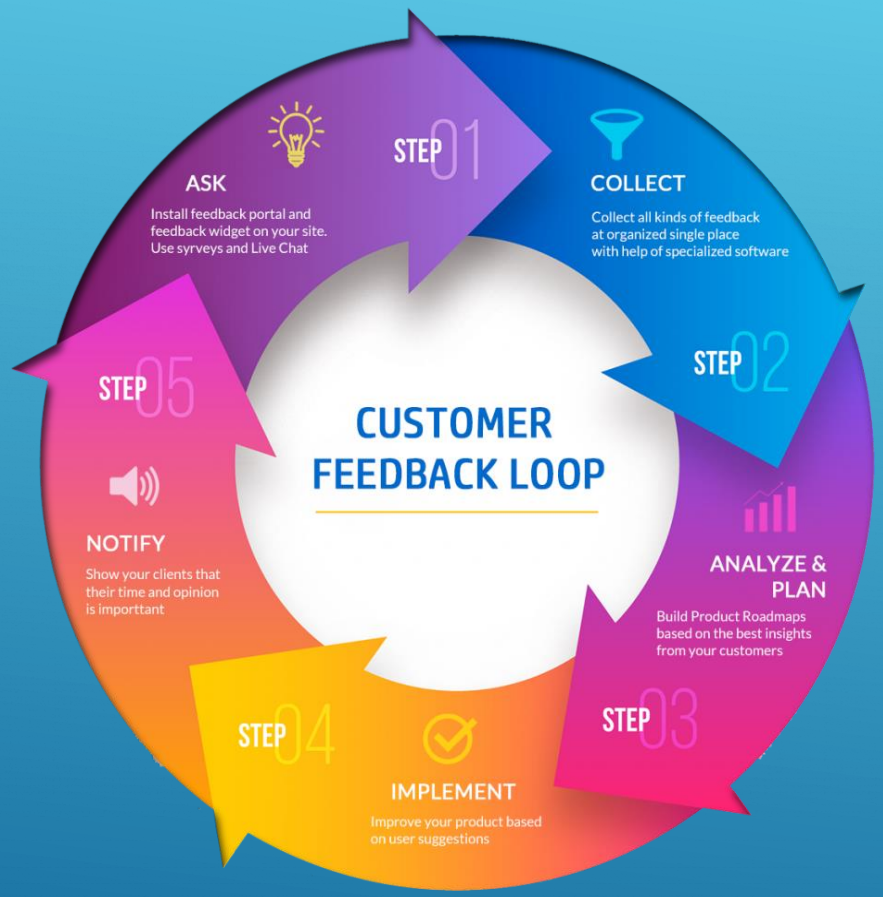
# MORE METRICS TO GAUGE AND SUSTAIN A QUALITY CULTURE

- The latest literature reflects an evolving paradigm: rather than relying solely on error rates and compliance scores, organizations are increasingly seeking to **monitor the "health" of their quality culture** through a blend of leading and lagging indicators, leadership alignment metrics, employee engagement scores, and the integration of real-time digital data. This multifaceted approach, backed by emerging research and digital tool innovation, provides a roadmap for organizations to proactively cultivate and sustain a robust quality culture that drives continuous improvement and operational excellence.
- By adopting a balanced, integrated metrics system, one that couples quantitative data with qualitative insights, organizations can not only detect early signs of cultural drift but also reinforce the behaviors and practices that support long-term quality, operational excellence and business performance.

# METRICS: IN CONCLUSION

Many of the following Best Practices presented here have common aspects regarding how they help build and maintain a quality culture.

# BEST PRACTICES FOR MAINTAINING YOUR QUALITY CULTURE

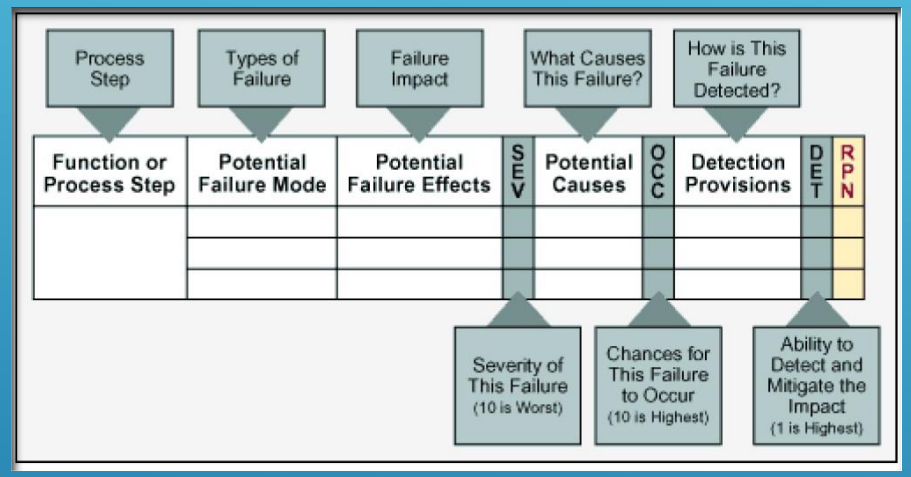



A **customer-centric culture** doesn't just complement a quality culture - it actively reinforces it. By focusing on customer engagement and satisfaction, organizations naturally adopt practices that emphasize performance, efficiency, improvement and accountability, all of which are foundational to quality.

So, as a best practice, a laboratory needs to focus on customer feedback, customer insights, customer satisfaction and the overall customer experience, as a key driver of the laboratory's quality culture and operational excellence.

Take **actions**, at your laboratory, to make such a focus an organizational reality!

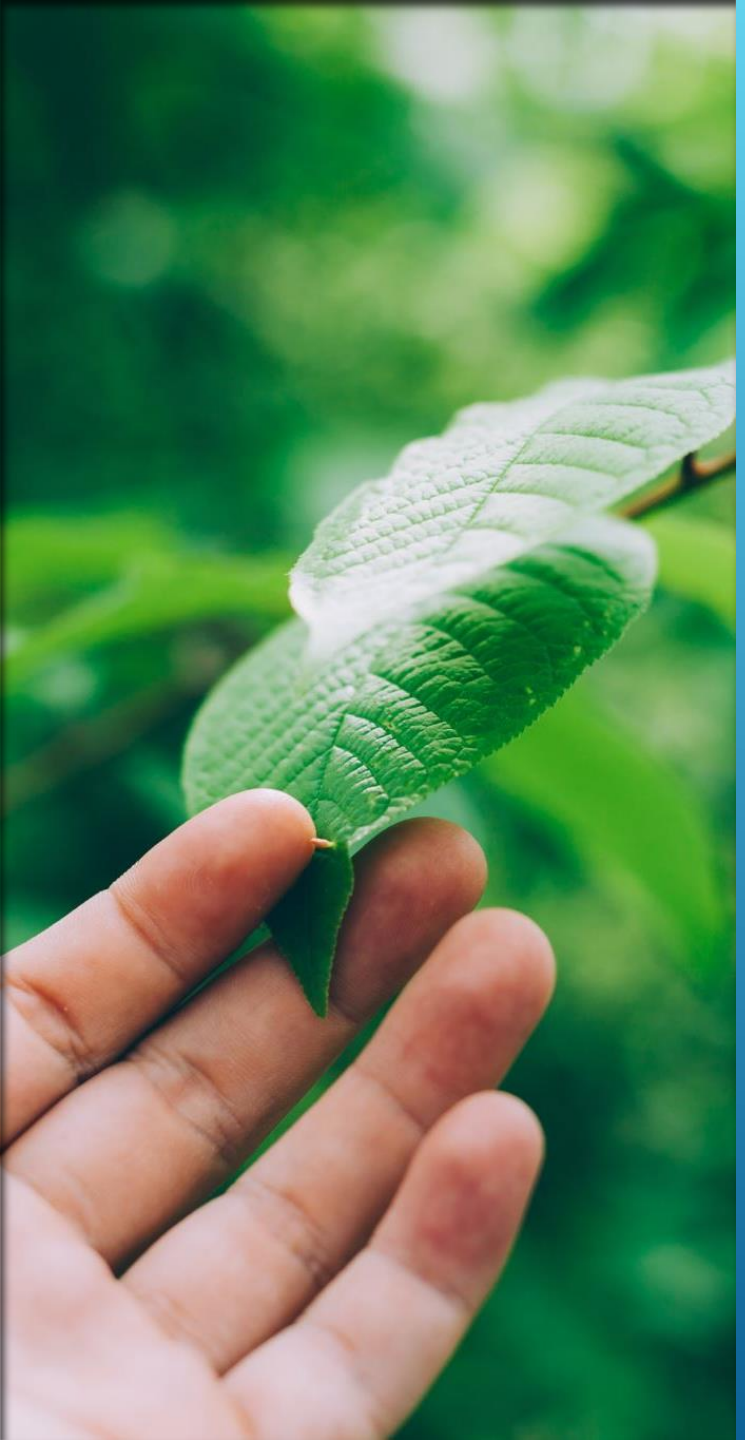
# BEST PRACTICE - FOCUS ON THE CUSTOMER




- How Being Risk-Aware Contributes to a Quality Culture
  - Proactive Prevention Practices to Anticipate Errors
  - Data-Driven and Quantitative Risk Analysis Tools
  - Accountability and Ownership
  - Alignment with Standards (ISO 17025, ISO 9001:2015)
  - Driver of Continuous Improvement Loop

By weaving risk management into the fabric of daily operations, organizations nurture a quality culture characterized by foresight, rigor, collaboration, and relentless improvement.

# BEST PRACTICE – RISK MANAGEMENT



- In essence, **sustainable practices** - those that balance environmental stewardship, social responsibility, and economic viability - not only drive long-term organizational resilience but also cultivate the underlying values, behaviors, and processes that characterize a quality-focused culture.
- By embedding sustainability into everyday operations and decision-making, organizations foster continuous improvement mindsets, galvanize employee engagement around shared ideals, enhance operational efficiency, and bolster stakeholder trust. All hallmarks of a mature quality culture.

# BEST PRACTICES – PROMOTE SUSTAINABLE PRACTICES

# BEST PRACTICE - DIGITAL TOOLS AND REAL-TIME DATA INTEGRATION

Advancements in digital technology now allow quality managers to establish real-time quality culture monitoring systems. These platforms:

- **Automate Data Collection:** Integrate with internal communication platforms, LIMS, LMS (learning management systems - AI driven), and quality management systems (QMS) software to continuously measure key performance indicators.
- **Visualize Data Effectively:** Provide dashboards that highlight trends, performance indicators, enabling both leadership and teams to react rapidly when early indicators show signs of cultural drift.
- **Benchmark:** Use benchmarking studies to see how your quality culture metrics compare with industry best practices.

# BEST PRACTICE - RECOGNITION AND REWARD OF PEOPLE AND TEAMS

- Publicly recognize individuals or teams who identify risks early or propose impactful improvements, reinforcing that proactive quality efforts are valued LGC Clinical Diagnostics Blog.
- Create a "Quality Hero" award or similar peer-nominated program to celebrate behaviors that exemplify your lab's values and quality culture mindset. MedicalLab Management.
- Regularly communicate quality improvements, advancements and success stories to stakeholders (e.g., all employees, clients)
- Publicly acknowledge and reward quality champions and efforts (both individuals, teams and labs)
- Create monetary and non-monetary recognition programs that reinforce quality behavior.
- Have **fun** events to celebrate!

"System makes it Possible.

Culture makes it Real."

# QUALITY MANAGEMENT SYSTEM ELEMENTS THAT HELP MAINTAIN YOUR QUALITY CULTURE

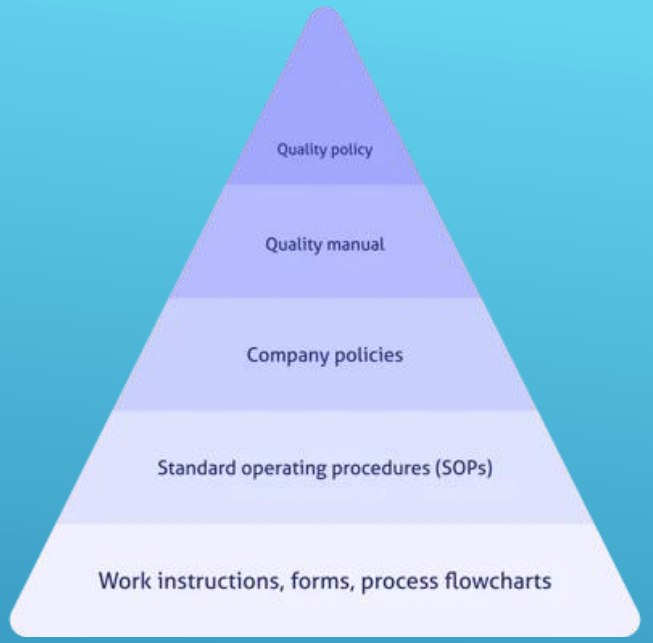
# WHAT IS A QUALITY MANAGEMENT SYSTEM (QMS)

- A structured and integrated framework of processes and procedures.
- Ensures consistent delivery of accurate and reliable results. Which in turn builds trust.
- Aligns with TNI Standard, DoD and ISO/IEC 17025 for testing laboratories.
- Which QMS elements are key to building and maintaining your quality culture.

# DOCUMENTED PROCEDURES (E.G., STANDARD OPERATING PROCEDURES AND QUALITY MANUALS)

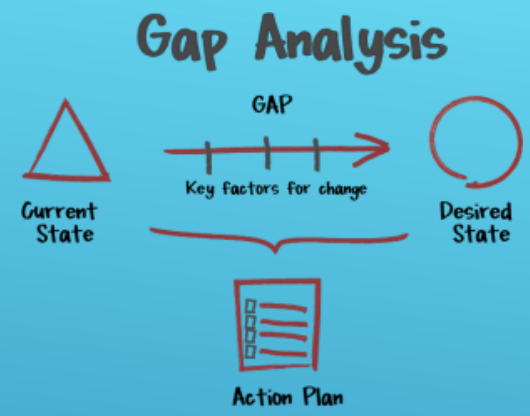
- Define SOPs and their role in maintaining consistency and their role in the QMS.
- Ensure efficient, effective SOP development, implementation and updates.
- Document Control (maintain a traceable system)
- Consider using QMS software program!

***A well-developed documentation system not only provides clarity but also forms the basis for audits, training, and process improvement. All these elements help maintain your quality culture.***



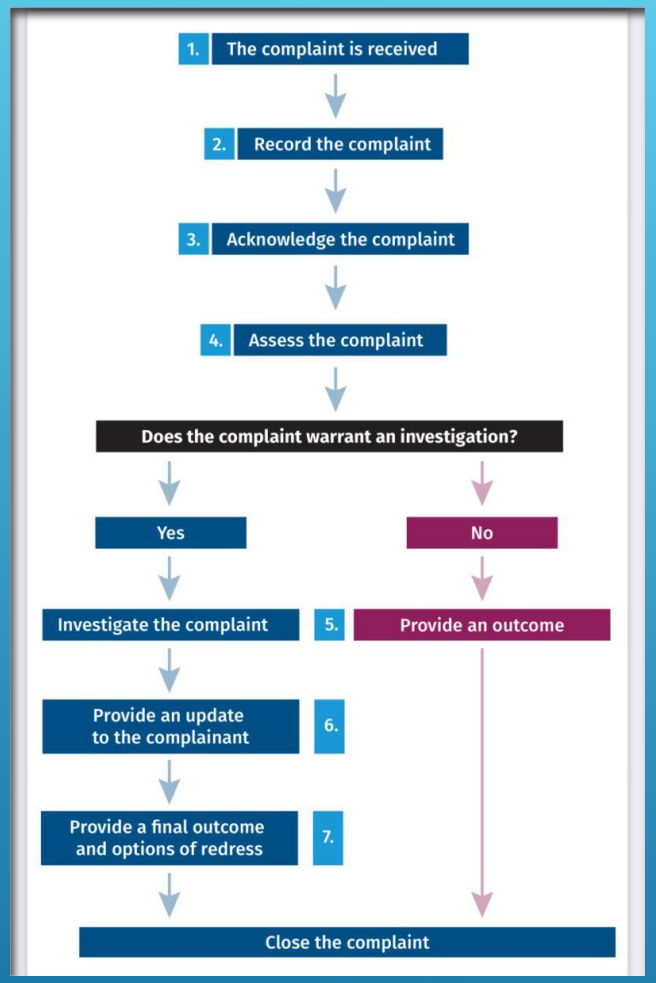
# INTERNAL AUDITS AND MANAGEMENT REVIEWS

- Regular assessments help identify risks, gaps and verify compliance with standards.
- Helps monitor performance and weakness in the QMS and shifts in the culture.
- Audits feed directly into the risk management, corrective action and continuous improvement processes.
- They act as another feedback loop.
- Regular assessments and reviews reinforce personal responsibility among staff and help build a culture where quality issues can be raised and addressed without fear (if approached and done correctly).




- Trend Analysis to detect and record out of control situations before they occur.
- Root cause analysis to prevent recurrence.
- Use problems, systematic errors and non-conformances as an opportunity to improve.
- The opposite (quick fix) can grate away at the quality culture.

# CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)




- Customer complaints literally provide your laboratory a golden opportunity to help maintain your quality culture and improve upon it.
- It provides another window to be customer focused and address customers needs.
- An effective complaint process that incorporates responsibility and accountability only builds on the mindset and behaviors needed for your quality culture.
- Failure of the complaint process erodes trust, stifles improvement, promotes complacency and increases customer churn. You then build a negative reputation, when you don't listen to your customers problems and concerns.

# CUSTOMER COMPLAINT PROCESS

- A well thought out and implemented data integrity policy and program provides a strong foundation for your quality culture.
- However, it requires continuous training and implementation. For it to work, it must be a dynamic process.
- The next table shows how a data integrity program supports your culture.

# DATA INTEGRITY PROGRAM

***"THE FINAL DATA IS ONLY AS GOOD AS THE WEAKEST LINK" EPA - REGION 5***

| Data Integrity Program Component | Supports Quality Culture by… | Mapped to Standards |
|---|---|---|
| 1. Controlled Access to LIMS | Ensures only authorized users can enter/edit data, promoting accountability | - **ISO/IEC 17025 §7.11.2** – Data protection - **TNI EL-V1M2 §5.10.8.1** |
| 2. Automated Audit Trails | Tracks all data changes, deters misconduct, and ensures traceability | - **ISO/IEC 17025 §7.5.2** – Records of original observations - **TNI EL-V1M2 §5.10.8.3** – Electronic data audit trails |
| 3. Data Review & Verification Checkpoints | Builds shared responsibility and reinforces rigorous review | - **ISO/IEC 17025 §7.1.5, §7.8.7** – Review and authorization - **TNI EL-V1M2 §5.5.6** – Independent technical review |
| 4. Change Control Procedures | Prevents unauthorized or inconsistent changes to methods or data | - **ISO/IEC 17025 §7.11.1, §7.11.4** – Prevent unauthorized changes - **TNI EL-V1M2 §5.10.8.6** – Method updates and version control |
| 5. Secure Data Backups & Archiving | Protects data integrity and ensures results can be verified later | - **ISO/IEC 17025 §7.11.5** – Protection and retrieval of records - **TNI EL-V1M2 §5.10.8.5** – Backup and recovery procedures |
| 6. Data Integrity Training & Ethical Declarations | Promotes awareness, personal responsibility, and ethical conduct | - **ISO/IEC 17025 §6.2.5** – Competency and ongoing training - **TNI EL-V1M2 §5.2.7** – Training and documentation |

# "CULTURE EATS STRATEGY FOR BREAKFAST"

PETER DRUCKER

At environmental testing laboratories, it's just as true.

Yes, Compliance, QMS, Best Practices and KPIs are all essential.

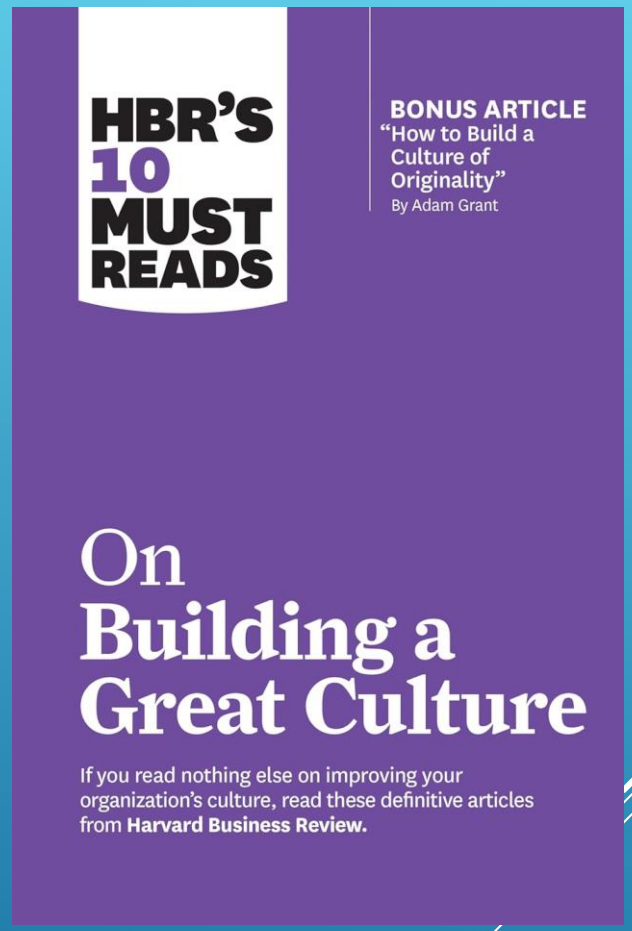
**But without a culture, none of it sticks!**

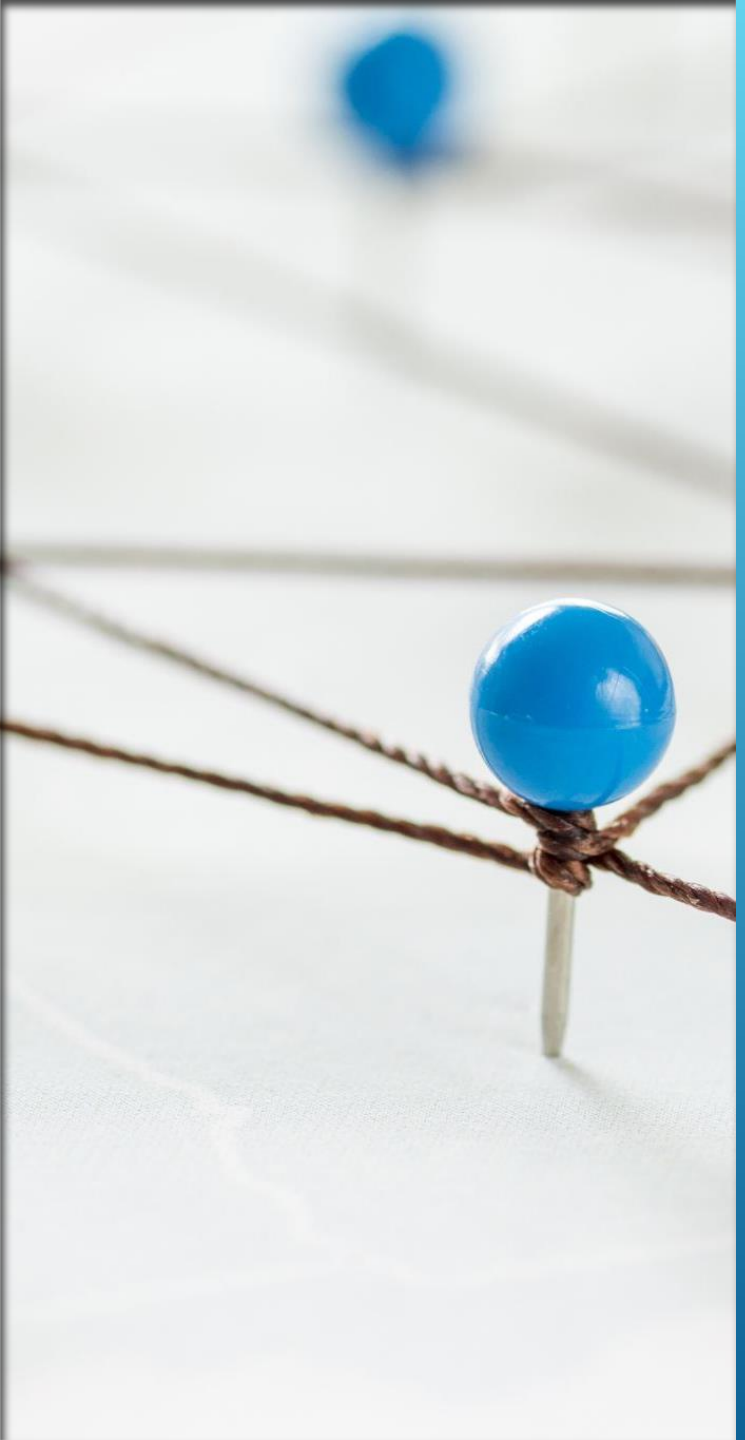
So, the laboratories that take **actions** to foster and maintain a strong quality culture tend to exceed mere compliance, integrating quality into everyday practices rather than treating it as they would a regulatory requirement.

In short, quality culture is the pervasive commitment to excellence that transforms quality from a mere process into a core organizational value and mindset.

**Now, ask yourself, what can be done to help maintain it at our environmental testing laboratory?**

Must Read!





# TO LEARN MORE:

- https://www.aihr.com/blog/culture-metrics/
- https://www.nsf.org/knowledge-library/optimizing-organizational-performance-importance-quality-culture
- 19 Culture Metrics To Track When Measuring Company Culture – AIHR
- https://www.researchgate.net/publication/374564905_The_Role_of_Quality_Culture_in_Determining_Organizational_Performance_A_Systematic_Review
- https://www.quality.org/article/using-iso-10010-build-effective-quality-culture#:~:text=Actions%20to%20achieve%20desired%20quality,culture

# Thank You

IT'S BEEN A GREAT RIDE!
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