A Case for Lean Compliance

Many organizations in highly regulated high-risk industries are finding that they are not able to keep up with all their obligations coming from external as well as internal sources.

Much of this can be attributed to a changing regulatory landscape where traditional approaches to compliance are no longer effective. Doubling down on audits and inspections across compliance siloes is too slow and too late to drive needed improvements, let alone contend with compliance risk.

Keeping organizations between the lines and meeting all stakeholder promises can no longer be considered an afterthought. Something else is needed.

To understand what compliance now requires we need to look more closely at how regulations have changed.

A Changing Regulatory Landscape

Over the last decade regulators have started to modernize their programs to become more risk-based; moving towards performance and outcome based designs. The desired effect of this transformation is to achieve better outcomes with respect to public safety that could not be achieved by prescriptive rules alone.

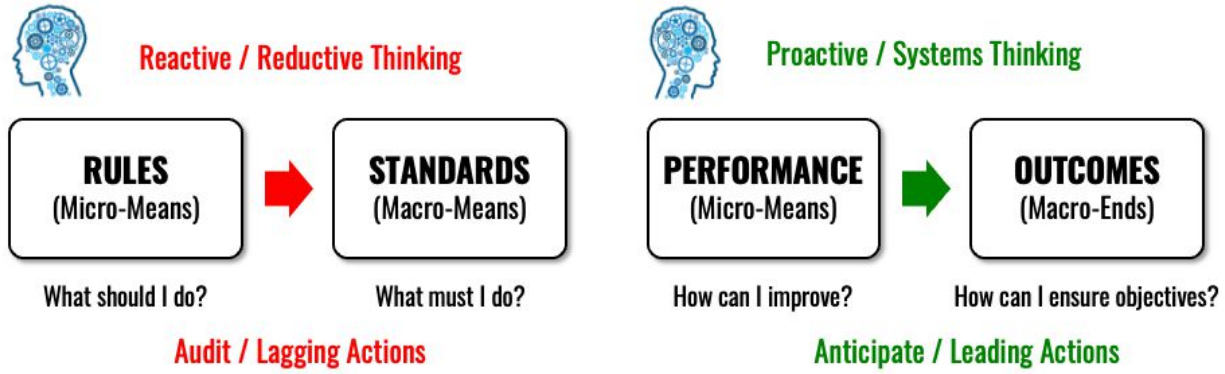

Figure 1 - Regulatory Landscape

This resulted in transferring accountability for public risk to a larger degree from government agencies to industry and individual companies.

New Regulatory Designs

Adapting to the new regulatory designs would come at a cost and would take time. Organizations needed to adopt a different mindset, skills, and practices which many did not have or have the time to learn.

Fundamentally, organizations would need to become more proactive with their compliance. They would have to anticipate rather than merely react. Instead of audits as the trigger for change, organizations would be expected to conduct their own assessments, set their own compliance goals and objectives, establish risk measures, and measure progress towards targeted outcomes. Organizations under a risk-based regime would need to regulate themselves.

The role of regulators would focus now towards validating outcomes instead of verifying conformance to procedures. However, more importantly, they would need to work with industry to establish targets and foster support. Regulators would be, in a manner of speaking, more concerned about the "ends" rather than prescribing the "means".

Reacting To the New Landscape

The downstream effect to risk-based regulatory designs have caught many organizations off guard; too busy fighting fires to have any time to be proactive and adopt new kinds of obligations.

Even when organizations wanted to be forward-thinking, they found it difficult to envision what being proactive looks like having spent many years under the tutelage of prescriptive rules. It is not surprising that many would simply double down on inspections and audits since that was the hammer they knew and could acquire more of.

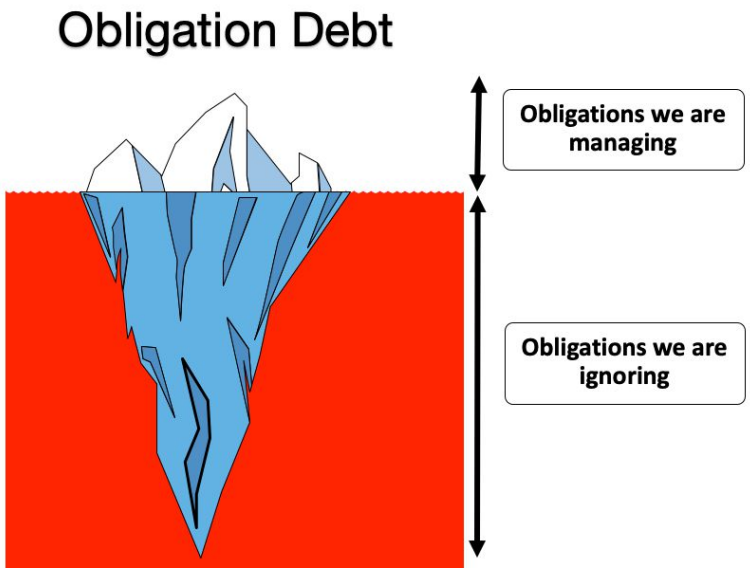

Figure 2 - Obligation Debt

Given that it is impossible to inspect everything, most organizations prioritize efforts on a portion of their obligations associated with mandatory requirements ignoring most if not all voluntary commitments and promises. The number of obligations “underwater” can be as much and often more than the ones that are being managed.

How can organizations deal with the sizeable number of unmanaged obligations and adapt to the new regulatory designs?

A Different Approach is Needed

Adapting to modern regulatory frameworks requires a transformational change to how compliance is done. However, for many organizations, improvements to compliance are funded from existing budgets using existing resources. Not the best conditions for a successful transformation.

Fortunately, these are the conditions where LEAN has excelled as evidenced in automotive, health care and more recently in construction, oil & gas, banking, and other sectors.

Could LEAN also be effective to transform compliance?

A Case For LEAN

To better understand how LEAN could help we need to go back to the early days of LEAN when it was first introduced by Taiichi Ohno at Toyota in the1950s. Taiichi Ohno, the father of LEAN, taught about the removal of waste, standard work, and continuous flow. However, that is only part of his story.

Ohno also taught that the production leader is the one who "breaks" the standard. When you make an improvement, you take out your very best person from the line. It is what that person did next that was transformational.

Freed up resources worked on further improvements that resulted in even more people removed from the line. In the end, Ohno would have enough people to start an entire second production line. Instead of fractional improvements he was able to double his capacity.

Now, imagine if organizations followed the same approach for compliance. They would still reduce waste, standardize work, and streamline the work. However, that too would only be part of what is possible.

Freed-up resources from the reactive side of compliance (read audits) could be moved over to the proactive side. They could anticipate changes, address root causes, and introduce new capabilities to always stay in compliance.

If organizations did this, they could also double their capacity to meet compliance obligations. They would have the capacity to manage all their obligation debt.

This is exactly what compliance now needs, but not without first addressing LEAN's blind-spot.

LEAN's Blind Spot

LEAN is well known for improving productivity. However, when it comes to such things as inspections and audits these are seen as waste and something to be eliminated.

For LEAN to have a transformational effect we need to understand that compliance and manufacturing have more in common than most realize.

LEAN fundamentally is concerned with removing variation from processes. Compliance is also concerned with this but calls in uncertainty. Variation and uncertainty are two sides of the same coin. Instead of defects resulting from variation, compliance focuses on non-conformance resulting from uncertainty.

Risk is the effect of uncertainty and is the waste we need to eliminate or reduce. LEAN and compliance could now be on the same page.

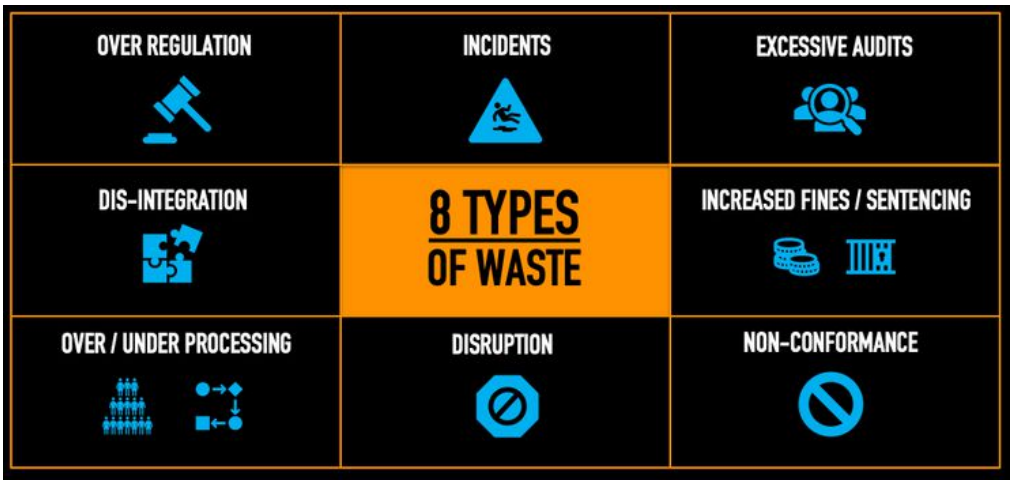

Figure 3 - Compliance Waste

Adding Risk Management To LEAN

Reducing compliance waste (i.e., risk) now becomes the mandate for lean practitioners working in compliance domains including environmental, safety, security, quality, ethics, and regulatory programs.

ISO 31000 defines risk as the uncertainty on objectives. Broadly speaking, uncertainty takes the form of epistemic uncertainty (lack of knowledge) which you buy down and aleatory uncertainty (having to do with chance and variability) which you treat with margins.

This differentiation can be visualized using the following modified version of Michael Porter's Value Chain Analysis (VCA):

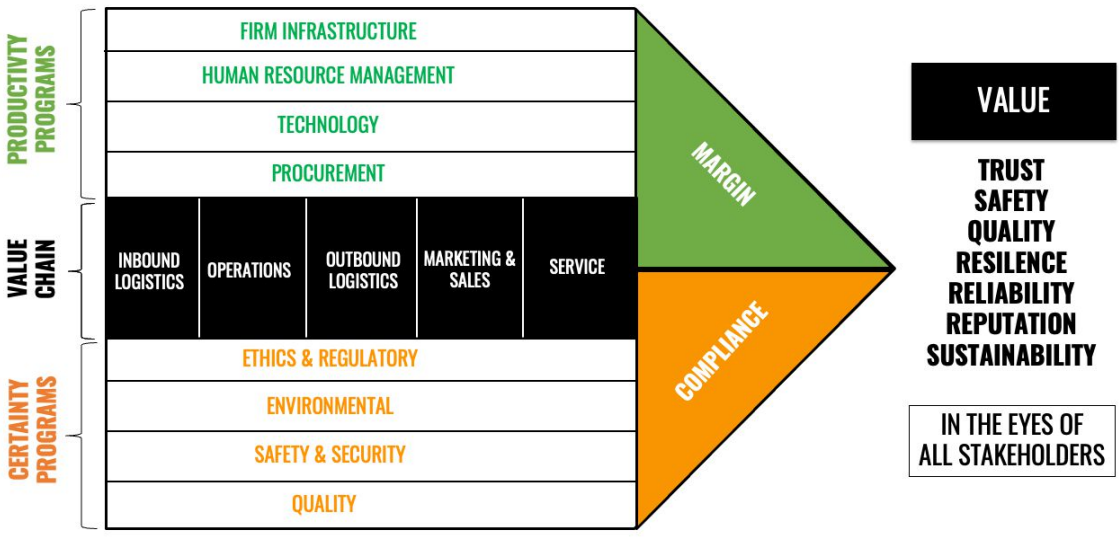

Figure 4 - Compliance Value Chain

LEAN applied across the organization helps improve efficiencies which improves margins buffering against the effect of irreducible risk. However, it can also be used to fund buying down reducible risk. LEAN can create the opportunity for compliance improvements.

A portion of this margin can be used to fund proactive measures to drive down risk by improving the certainty of meeting obligations. In other words, compliance can be more effective to help organizations stay between the lines and achieve the outcomes it does want and avoid the ones it doesn't.

Operational Compliance

To realize compliance benefits, compliance must work. This means compliance must be more than a disparate set of practices, or something tacked onto the end of a process. Instead, it must be a system of processes that work together to increase the certainty of achieving compliance objectives and outcomes.

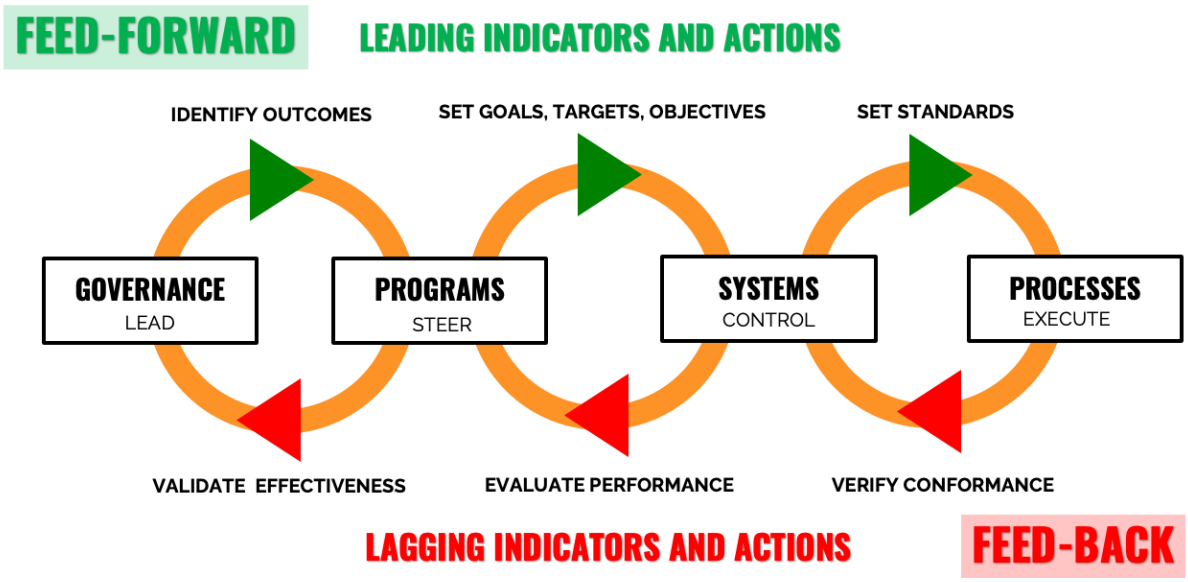

Figure 5 - Operational Compliance Model

The function of compliance must:

- Have identified outcomes, goals, targets, objectives, and standards
- Encompass feed-forward processes that steer towards goals and objectives.
- Include feed-back processes to correct for deviations from planned targets.
- Consistently meet performance levels to achieve intended outcomes.
- Consistently conform to standards
- Make progress towards targeted outcomes
- Continuously improve across all levels of management.

If this looks like a manufacturing system, you are getting the idea.

Operational Readiness

To achieve operational readiness, many take a phased: component first-approach. This comes from years of prescriptive obligations and a focus on implementing "shall statements" to pass certifications and audits.

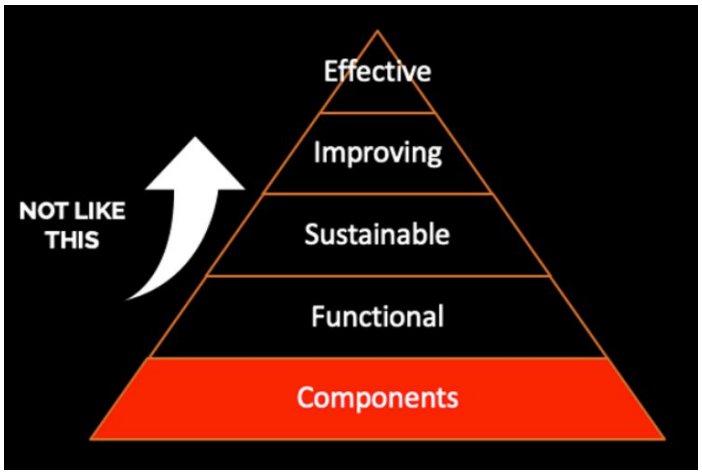

Figure 6 - Component First Approach

When the focus is on meeting "shall statements" rather than improving outcomes, we find these familiar steps:

- Understand the components of the regulation or standard.
- Map existing practices to the components / elements.
- Identify where current practices do not meet the standard.
- Engage these deficiencies in a Plan-Do-Check-Act (PDCA) cycle.

This approach is not without its limitations the most significant being that it often fails to deliver operational systems fast enough or at all.

Organizations usually run out time, money, and motivation to move beyond the parts of a system to implementing the interactions which are essential for a system is to be considered operational.

For compliance to be effective in the new landscape another strategy is needed that:

- Creates and sustains essential properties over time,
- Achieves operational status sooner,
- Provides a platform for continuous improvement with the least cost

We know from systems theory that systems are never the sum of its parts but rather the product of its interactions. It is these interactions that cause emergent properties to be produced. For compliance systems these are the outcomes we are targeting: zero incidents, zero violations, zero fatalities, zero breaches, zero emissions, and so on.

You cannot implement a holistic system partially which unfortunately many end up doing.

Lean Compliance's approach builds on the work by Eric Reis (Lean Startup) that emphasizes system interactions to achieve operational status sooner than traditional approaches.

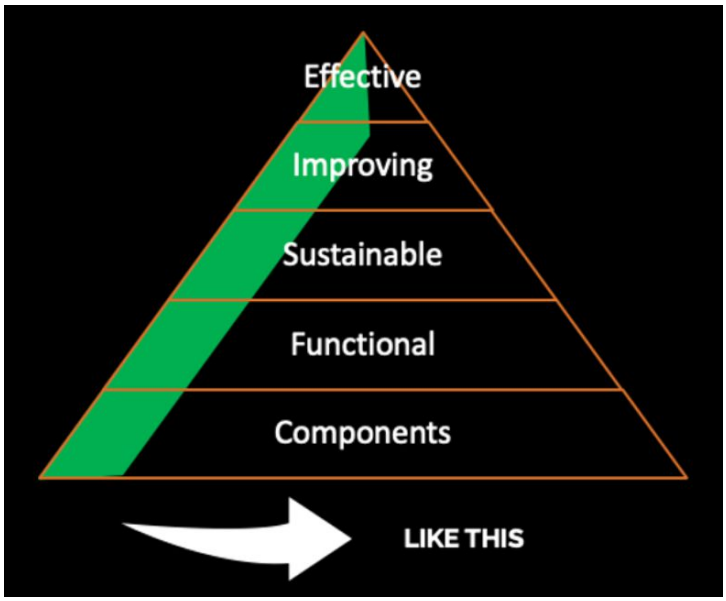

Figure 7 - Systems First Approach

This approach includes the following activities:

- Identify and evaluate mandatory and voluntary: prescriptive, performance, and outcome-based obligations.
- Map obligations to existing governance, programs, systems, and processes.
- Identify and evaluate measures of conformance, performance, effectiveness, and assurance.
- Identify and evaluate uncertainties to meeting targeted goals and objectives.
- Identify and evaluate capabilities, capacity, and performance to meet and sustain obligations.
- Implement a minimal viable compliance (MVC) based on essential behaviours and properties that can be improved on over time.
- Elevate compliance effectiveness by improving the MVC using a build-measure-learn process.

Following these steps produces compliance systems that might start off looking like a bicycle but will soon look like a motorcycle, and then a car, and so on.

What you will not have is an assortment of disparate compliance parts not working together that might someday be effective.

At every stage you will have a system capable of creating the outcome of compliance.

Continuous Value Assured by Continuous Compliance

To keep up with increasing and expanding obligations across regulatory and stakeholder expectations requires a different approach to compliance than used in the past.

Applying LEAN principles and practices adapted for compliance transformational benefits can be realized by:

- Eliminating waste
- Applying more resources to proactive measures

- Effectively contending with risk
- Properly servicing obligation debt
- Keeping stakeholder promises
- Staying between the lines
- Engendering stakeholder trust

Figure 8- Continuous Compliance

Organizations will have the assurance they need knowing with confidence that they were in compliance yesterday, in compliance today, and will be in compliance tomorrow.

Continuous Value assured by Continuous Compliance.

Compliance can finally fulfill its purpose to improve the probability of mission success by ensuring that value is always protected.