

Beyond Purchase Orders

Procurement is not solely accountable for the overall project's outcome, but it is responsible and accountable for the decisions and actions within its control.

From Assumption to Accountability

Procurement is often considered successful when it completes the core transactional work:

- Issues purchase orders on time
- Secures competitive pricing
- Ensures suppliers meet contractual requirements
- Receives goods as promised

These measures matter, but they only tell part of the story. Completing procurement tasks does not necessarily mean procurement has helped the project succeed.

Project outcome is a shared responsibility across the entire team. Still, procurement must remain accountable for the outcomes created by the decisions and actions within its control.

We need to change this perception and hold procurement accountable to the project for the outcome of its decisions. They do hold the power to determine or negotiate the commercial terms, negotiate delivery requirements, agree to specifications, allocate risks,

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Holding Procurement Accountable for Project Outcome

[By Steven G. Lauck | Value Transformation LLC](#)

and build the relationship with the supplier, so in many ways procurement can make or break the outcome of a project.

We need to be more open about the expectations and requirements for our procurement partners and make them accountable to the project for the outcome of their decisions. I think we can define those requirements in the areas below.

Project Expectations

The expectation is that the procurement team understands the project, knows the objectives of the project, and is involved early enough to influence the risks and outcomes of the project. The outcome of this is not just measured by the issuance of a PO.

We would measure it by:

- Did procurement understand the larger objectives of the project? They can't just understand what's written on the purchase requisition.
- Did procurement bring their market knowledge, product knowledge, commercial experience to the table, and challenge the assumptions and expectations?
- Did procurement support the selection of the best supplier for the project, not necessarily the lowest price? The lowest price does not always result in the lowest project cost, because the best supplier will add value, bring knowledge, and mitigate risk. The focus is not just on the purchase price, but on project outcome.
- Did procurement identify and explain risks, including risks of supplier finance, delivery, technical capabilities, lead times, capacity, or single source? And if there was only one supplier, why was there only one supplier and how could that risk be mitigated?
- Did procurement negotiate a contract that protects the company, but also allows for project outcome? The contract should not just focus on the commercial protection of the buyer, but on the overall outcome of the

project as well.

Outcomes of the procurement partner

If we want a successful project outcome we need the procurement department to demonstrate that they understood the project objectives, that they made smart decisions in terms of supplier selection, that they considered the risks to the project and made sound risk decisions, and that they helped to achieve a great overall outcome for the project.

Engaging Procurement

Engage them in the beginning with their attendance at the project kickoff meeting!

Having a buyer assigned to the project team, involved in the planning process, helps to bring the commercial risk of the project into the planning discussions, and helps them to understand the project objectives and their risk to the project. The buyer will help to challenge requirements, provide alternatives, and help build realistic schedules.

We can't expect procurement to succeed if we don't ask them to succeed, and we don't engage them in the process where they have influence over project risks. Procurement is a partner to the project that can help mitigate or increase risk. We should engage them and hold them accountable to the outcomes.

Conclusion

Inclusion is essential, but it does not happen automatically. Project leaders and management are responsible for bringing the right functions into the process. Procurement is responsible for contributing commercial expertise, engineering for making sound technical decisions, and operations for ensuring implementation readiness. Everyone shares responsibility for the project's outcome, while each function remains accountable for its own contribution.

Permission Is Not Conformance

Products and manufacturing processes do not always proceed exactly as planned. Materials become unavailable, tooling fails, suppliers propose substitutions, test results fall outside limits, and urgent production needs create pressure to move forward.

Organizations need controlled ways to address these situations. Deviations, waivers, Temporary Change Authorizations, and nonconformance reports provide those mechanisms—but they are not interchangeable. Each serves a different purpose, and none should become an informal substitute for engineering discipline or configuration control.

The specific terminology varies by company, industry, customer, and contract.

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Deviations, Waivers, and Temporary Changes

By Jon M. Quigley, PMP, CTFL | Value Transformation LLC



What matters is that each term is clearly defined and connected to requirements, risk assessment, authorization, traceability, testing, and closure.

A Nonconformance Describes a Condition

A nonconformance exists when a product, process, material, document, or test result does not meet a specified requirement. The requirement may come from a drawing, specification, work instruction, Control Plan, purchase order, regulation, or customer requirement.

A nonconformance report records what happened. It should identify the affected requirement, actual condition, part numbers, revisions, quantities, serial or lot numbers, and the location of the affected items.

The material or product should be identified and controlled to prevent unintended use while the organization determines its disposition. Possible dispositions include:

- Rework to bring the item into full conformance
- Repair to make it acceptable for its intended

use

- Use as-is under an approved concession or waiver
- Return to the supplier
- Scrap

Rework, repair, and use-as-is are not the same decision. Rework restores conformance to the original requirement. A repair may make the product usable without fully restoring the original condition. Use-as-is accepts the known departure without modifying the product. The required authority and supporting evidence should reflect those differences.

A Deviation Authorizes a Planned Departure

A deviation is generally used when the organization knows in advance that it cannot, or does not intend to, meet an approved requirement in a limited situation. Approval is requested before the affected product is built, processed, or delivered.

For example, a supplier may request permission to use an alternate material

Permission Is Not Conformance

because the specified material is temporarily unavailable. Manufacturing may need to use different equipment while the approved machine is being repaired. Engineering may authorize a temporary inspection method while production tooling is being completed.

A deviation should define:

- The requirement from which the organization will depart
- The proposed alternate condition or method
- The reason for the request
- The affected product, process, quantity, lot, or time period
- The risks created by the departure
- Additional inspection or testing requirements
- Required internal, supplier, regulatory, or customer approvals
- The expiration and return-to-standard plan

A deviation is permission for a specific departure. It does not permanently change the approved design or process baseline.

A Waiver Addresses Acceptance

The term waiver is often used to authorize acceptance or release of a product that does not fully meet a specified requirement. In many

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Controlling Exceptions with Evidence and Traceability

organizations, it is applied after the nonconforming condition has been identified, although contractual definitions may differ.

A waiver should not be approved merely because the product is urgently needed. The decision should be supported by engineering analysis, risk evaluation, inspection results, test evidence, and an understanding of the product's intended application.

The review should consider more than immediate function. A departure may also affect durability, serviceability, interchangeability, safety, regulatory compliance, appearance, future repairs, or downstream assembly.

Permission to ship does not mean the product suddenly conforms. The record must preserve what was accepted, why it was accepted, who approved it, and which products were affected.

A useful shorthand is:

Deviation = permission to depart before the event.

Waiver = permission to accept after the event.

Temporary Change Authorization Controls an Interim Change

A Temporary Change Authorization, sometimes called a TCA, allows a controlled, time-limited change to an approved design, process, material, supplier, tool, test method, or work instruction.

The key word is temporary. The authorization must have defined boundaries and a clear end condition. It should identify when the change begins, what units or operations it affects, how the changed condition will be identified, what verification is required, and how the organization will return to the approved baseline.

A TCA may require temporary revisions to:

- Drawings or specifications
- Bills of material

- Work instructions
- PFMEAs and Control Plans
- Inspection and test procedures
- Labels, routing instructions, or traceability records
- Supplier or customer documentation

Without these connections, the temporary change may exist only in an email while the production documents continue to communicate something different.

Exceptions Require Evidence and Traceability

These mechanisms are valuable because they allow an organization to respond to real conditions without losing control. The danger comes when temporary approvals become routine workarounds.

Every deviation, waiver, TCA, and nonconformance should be traceable to the affected requirement and configuration. The decision should identify who has the authority to approve it, what evidence supports it, what additional controls are necessary, and when the authorization ends.

The review may also require updates to the DFMEA, PFMEA, Control Plan, test plan, work instructions, supplier requirements, or PPAP documentation. If the changed condition introduces a new failure mode or alters an existing control, the risk analysis must change with it.

When Temporary Becomes Permanent

Repeated deviations and waivers are important signals. They may indicate an unrealistic requirement, an unstable design, poor process capability, inadequate supplier control, or a configuration that no longer represents what is actually being produced.

At that point, the organization should either correct the condition or formally change the requirement through the established engineering-change process. Continuously

Permission Is Not Conformance

renewing a temporary authorization does not create control. It hides the absence of it.

The objective is not to eliminate every exception. The objective is to ensure that exceptions are visible, evaluated, authorized, traceable, tested, and closed. Permission may allow work to continue, but permission is not the same as conformance.

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Controlling Exceptions with Evidence and Traceability

Attribute	Deviation	Waiver
Primary purpose	Authorizes a planned departure from an approved requirement	Authorizes acceptance or release of an item that does not meet a requirement
Typical timing	Requested before manufacturing, processing, or delivery	Requested after the nonconforming condition is discovered
Product condition	The affected product may not yet exist	The affected product has typically already been produced
Trigger	A known inability or reason not to follow the current requirement	An actual nonconformance identified through production, inspection, or testing
Example	Approving an alternate material before building a defined lot	Accepting a completed lot with a dimension outside specification
Starting document	Deviation request or temporary authorization	Nonconformance report, followed by a waiver or concession request
Required evidence	Risk analysis, engineering review, proposed controls, and verification plan	Inspection results, test evidence, engineering assessment, and fitness-for-use evaluation
Scope	Defined parts, lots, quantities, processes, locations, or time period	Specific completed parts, serial numbers, lots, or shipments
Approval question	"May we depart from this requirement under these conditions?"	"May we accept or release this known nonconforming product?"
Effect on requirements	Does not permanently revise the approved requirement	Does not make the nonconforming item conform to the original requirement
Additional controls	May require added inspections, tests, identification, or process controls	May require sorting, additional testing, usage restrictions, or customer notification
Duration	Temporary and subject to an expiration date or quantity limit	Limited to the specifically identified nonconforming product
Traceability	Must identify everything produced under the approved deviation	Must identify every nonconforming item accepted under the waiver
Closure	Expires when the defined period or quantity ends, or the approved baseline is restored	Closes when the affected product is dispositioned and all required approvals are recorded
Repeated use	May indicate the requirement or approved process needs formal revision	May indicate poor process capability, inadequate controls, or an unrealistic requirement
Customer approval	Required when customer requirements, contracts, safety, fit, function, or regulated characteristics are affected	Commonly required before shipping customer-owned or customer-specified nonconforming product

ATTI Event Promotion

At this year's [Future of Automotive Testing Conference](#), which will take place at Automotive Testing Expo North America in October, ATTI will be joined onstage by Jon M. Quigley, former Volvo engineer and owner of Value Transformation, looking ahead at the insights testing can provide, the insights it cannot provide, and why transparency will become increasingly important when the evidence challenges what is believed.

The discussion will examine:

- Why transparency, communication and trust are important
- The different definitions of transparency
- What can happen when trust and transparency break down

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Testing, Transparency, and Trust

By Jon M. Quigley

- How companies can improve communication and reduce silos from cultural and toolchain perspectives
- Where and how data enters the picture
- Who should have access to data
- US laws addressing transparency and whistleblower protection

One of the hardships the discussion will explore is how seemingly reliable test data can lead teams to the wrong conclusions when the conditions behind that data are not properly understood or communicated.

"Weak configuration management can cause teams to compare results from different hardware, software, calibration, equipment, or environmental conditions. The result may look precise while answering the wrong question."

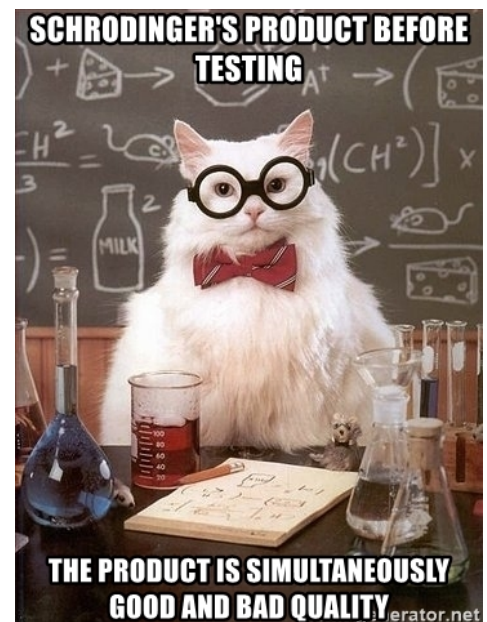
Quigley also highlights the importance of maintaining context as data moves between different tools and systems, particularly as more of these processes become automated.

"Use common identifiers and metadata so context survives movement between tools.

Automate routine transfer, but retain human review of meaning, uncertainty, and risk."

Ultimately, the discussion will look beyond the technology itself to consider how organizations can build greater trust in the evidence they generate – and what happens when that trust breaks down.

Join ATTI and Jon M. Quigley at Automotive Testing Expo North America, which takes place at the Vision Credit Union Showplace on October 27-29. It's free to attend – register now



October 27–29 Automotive Testing Expo North America

FMEA Is Not Stand-Alone

An FMEA should never exist as a stand-alone document. It is not an administrative exercise performed only to satisfy a customer, auditor, or quality-system requirement. The value of an FMEA comes from how it influences the work around it—and how evidence from that work flows back into the analysis.

The DFMEA must be connected to engineering, design decisions, and design testing and verification. The PFMEA must be connected to manufacturing-process development, the Control Plan, and process validation testing. Together, these activities form a continuous system for identifying risk, testing assumptions, establishing controls, and learning from actual results.

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Connecting Design, Testing, and Process Control



DFMEA Begins with Engineering and Design

The Design Failure Mode and Effects Analysis starts with the product's intended functions and requirements. The team considers how the design could fail to perform those functions, the effects of each failure, the potential causes, and the controls available to prevent or detect the problem.

This analysis should influence engineering decisions while the design can still be changed. It may lead to different materials, tighter or more appropriate tolerances, improved interfaces, additional diagnostics, better environmental protection, component changes, or modifications to the system architecture.

A DFMEA completed after the design is released may document risk, but it has limited opportunity to reduce that risk. The DFMEA must be integrated into the actual engineering process—not added after the important decisions have already been made.

Connecting DFMEA to Engineering and Design Testing

The DFMEA identifies risks, assumptions, and areas of uncertainty. Engineering and design testing provide evidence about them.

Early engineering testing may include simulations, calculations, prototypes, bench testing, software-in-the-loop, hardware-in-the-loop, environmental testing, and subsystem evaluations. These activities help the team understand how the design behaves and allow learning while change is still relatively inexpensive.

Formal design verification then confirms whether the product meets its documented requirements. Design validation examines whether the product performs as intended in its actual or representative application.

If the DFMEA identifies a thermal risk, the test program should evaluate credible loads, ambient conditions, duty cycles, and potential cooling failures. If connector retention is a concern, testing may need to include vibration, mechanical loading, assembly variation, environmental exposure, and repeated connection cycles. If software is

FMEA Is Not Stand-Alone

expected to detect and respond to a hardware fault, the test strategy should include fault injection and confirmation of the system response.

The relationship also works in the opposite direction. Test failures and unexpected results should feed back into the DFMEA. Testing may reveal a previously unidentified failure mode, an incorrect assumption, a new cause, or an ineffective control. The DFMEA, requirements, design, and test plan should evolve together as evidence is collected.

Moving from DFMEA to PFMEA

A design that performs correctly under test can still fail because it cannot be manufactured consistently. The Process Failure Mode and Effects Analysis considers how manufacturing, assembly, programming, inspection, handling, packaging, or transportation could create a defect or fail to prevent one.

Information from the DFMEA should flow into the PFMEA. People designing the manufacturing process must understand product characteristics important to function, safety, reliability, fit, or regulatory compliance.

These characteristics may include dimensions, material properties, torque values, crimp height, connector engagement, electrical

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One Connected Risk and Learning System

continuity, cleanliness, software versions, calibration values, or traceability requirements.

The PFMEA then asks how each process step could fail to achieve those characteristics. It evaluates the possible effects and causes and identifies prevention and detection controls. Manufacturing knowledge should also feedback to engineering. If a design characteristic cannot be produced or measured reliably, the best answer may be a design change—not additional inspection.

Connecting the PFMEA to the Control Plan

The PFMEA identifies process risk. The Control Plan defines how the selected controls will be executed during production.

The Control Plan should specify:

- What product or process characteristic will be controlled
- How it will be measured, tested, or verified
- The equipment or method that will be used
- The sample size and inspection frequency
- Who is responsible for the control
- What action will be taken when results are unacceptable

If the PFMEA identifies a significant control that does not appear in the Control Plan, work instructions, inspection process, or production test, the analysis has not reached the manufacturing floor.

The Control Plan should not be generic. Prototype, pre-launch, and production conditions may require different controls as the product and process mature.

Process Validation Testing Produces Evidence

The PFMEA and Control Plan describe how the process is expected to work. Process validation testing determines whether it actually works.

Producing one acceptable part does not demonstrate a capable and repeatable process. Validation should examine the process under intended operating conditions using representative materials, equipment, tooling, operators, software, work instructions, inspection methods, and production rates.

Depending on the process and its risks, validation may include first-article inspection, measurement-system analysis, gauge repeatability and reproducibility, machine or process capability studies, dimensional inspection, destructive testing, functional testing, run-at-rate evaluations, and production trial builds.

The results should confirm that the process can consistently produce output meeting the design requirements. When validation identifies variation, defects, or weak controls, the team should update the process, PFMEA, Control Plan, work instructions, and training—and then test again.

One Connected Risk and Learning System

The DFMEA, engineering testing, design verification, PFMEA, Control Plan, and process validation testing are not independent deliverables. They are connected parts of one risk-management and learning system.

The objective is not simply to complete the documents. The objective is to make better decisions, test assumptions, produce credible evidence, control manufacturing variation, and prevent failures from reaching the customer.

The DFMEA Came Too Late

The objective is to make better decisions, test assumptions, produce credible evidence, and prevent failures from reaching the customer.

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Risk Analysis Must Influence the Design

DESIGN RELEASED. TOOLING ORDERED. PRODUCTION STARTS MONDAY.



NOW LET'S IDENTIFY WHAT COULD GO WRONG.

About Value Transformation LLC

Value Transformation LLC helps organizations improve how they conceive, develop, test, launch, manufacture, and support products. We connect product and project management, systems engineering, supplier coordination, configuration management, quality, and testing so strategy becomes evidence-based execution.

Core capabilities

- Product and project management
- Testing, verification, and validation
- Supplier and multi-vendor coordination
- Product development and systems engineering
- APQP, PPAP, and quality improvement
- Training, coaching, and facilitation

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