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Process Change Assessment Techniques

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Executive Summary

Preventing process changes from causing unintended consequences is of increasing importance in establishing flawless mission success. These changes, often made in the name of improvement, continue to be identified as contributors to hard and expensive lessons as they can introduce unintended variables that can have adverse consequences for qualified hardware. Some process changes may also be labeled too quickly as having "no impact" or the changes may be seen as providing risks so low as to be "virtually inconsequential."

Negative consequences from process changes become more expensive the later they are detected. The impact is highest if the unintended consequence is seen during on-orbit operations of a space asset. It is notoriously difficult to ascertain and establish root cause for failures following launch. If the root cause is the result of a sub-tier or a supplier change to a process parameter, a processing material, or process method, the likelihood of establishing root cause may be remote.

This report compiled 22 examples of process escapes that resulted in adverse consequences. This data was analyzed for type of hardware, type of process, severity of the effect, and other categories. The categories are ranked into Pareto charts and provide insight into systemic reasons and circumstances for why process escapes continue to occur. The level of detail in many of the examples was insufficient to determine whether process change notification was supplied to the customer.

This report also identifies the types of process change assessment techniques currently available and in use by the space community as well as by several technical societies and standards organizations. The benefits and limitations of each technique will be described. A generalized set of assessment questions for methods, machinery, materials, and environment (principal elements in an Ishikawa or fishbone diagram) are also provided for selection/adaptation to specific scenarios. This report explores what types of process mitigation techniques are currently available and in use in the space community and compares these to techniques immediately available at key standards organizations.

The report looks into ways to flow down requirements to suppliers and sub-tiers to help mitigate risks from process changes.

Finally, the report proposes a framework or a plan to guide a processor on how to consider the impact of a proposed process change and how to assess the unwanted risks in advance so that mitigations can be developed and implemented.

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1. Background

Currently, space manufacturing product changes are assessed, defined, and categorized (as Class I or II) based on whether the change impacts form-fit-function or qualification (Class I). All other types of changes are classified as minor (Class II), and further limited to administrative or documentation clarifications and corrections. Process-related changes, however, do not receive the same level of disciplined review as an engineering change would receive as part of an engineering review board (ERB). Process changes, such as the change in the source of water used to manufacture resin, are either not well communicated to the prime/customer or not adequately evaluated for product impact (qualification and/or use). Some of these process changes are considered "innocuous" and may or may not be communicated to the customer. In addition, the customer may not adequately consider the change due to the aforementioned lack of a "formal board." Situations in which there are no contractual requirements for the customer to gain insight, review or approve product, or process changes pose additional challenges, and are beyond the scope of this particular product.

Additional requirements or elements of a Class I change can be further refined by the customer such as change or movement of manufacturing facilities, manufacturing processes, personnel, etc. Some of these changes may be considered inconsequential (not necessarily impacting form-fit-function) but could have a dramatic impact to the overall system.

It's impossible to provide a specification that covers all the attributes of a particular component in order to control and ensure compliance. Therefore, the impact and risk associated with a seemingly "inconsequential" change need to be fully communicated and assessed by the user.

While some manufacturing companies and primes may have their own internal guidelines for assessing process changes, there is no uniform consensus throughout the space community on a common methodology for assessing this risk. Neither is there common guidance to assist a supplier or processor on what questions to ask to assess the overall risk of a process change.

A conscientious supplier may not recognize that a change to an existing process represents a risk downstream or to potential customers. A supplier may not be cognizant of any "process changes" in its manufacturing, but if asked in a different way, may be able to identify "process improvements" that have been introduced as part of a typical learning curve or to reduce variation. As an example, perhaps a supplier has improved its throughput by running multiple batches concurrently through an oven when qualification was conducted with only one batch of material. Or perhaps a supplier may find it advantageous to alter the sequence of a particular build without considering or asking if there might be unanticipated consequences to the re-sequencing.

A customer, wanting to understand and mitigate the unintended consequences of a process change at a supplier, may be able to learn much more—and to teach a supplier more—about what constitutes a process change by asking the right questions. Through this dialogue, an understanding of how a device was qualified, what process changes have occurred since qualification, and the use of the device will help to identify whether a risk needs to be tracked or addressed. Both parties have a responsibility to share information and develop the appropriate risk mitigation strategy. Open dialogue and communication between a customer and the supplier and associated sub-tier suppliers will help to identify and mitigate process changes prior to escapes.

1.1 Scope

This report provides actionable recommendations, sources, and best practices for mitigating unintended consequences of seemingly inconsequential changes to space hardware manufacturing processes. The

report assimilated available guidance from several industrial associations as well as command media from space contractors to develop the recommendations. The report also reviews and analyzes more than 20 examples of unintended consequences resulting from intentional process changes to understand which common elements might be able to offer further guidance.

Process changes, for the purpose of this report, will be limited to those processes that are directly associated with the building of hardware. This report will not consider changes to processes that are not related directly to module manufacturing. For example, this report will not discuss changes to processes governing design controls, nonconforming hardware disposition, auditing, or other elements of a quality management system. Process changes within these supporting systems may also present opportunities for adverse consequences but are beyond the scope of this report.

Each prime or customer must weigh the impact to both themselves and to a supplier or processor before initiating a requirement for process change review. This document is not intended to be a "requirements" document; rather the intent is to provide guidance in the area of managing process changes and to point to some best practices that are available to manage process changes. Each prime or customer must determine how far into the supply chain "the notification and language of prior notification of process changes" must be applied.

The flowchart in Figure 1 illustrates two example paths of lower-level process issues which could escape detection until higher levels of integration.

Supply chain example: A prime or sub-tier supplier contracts with an outside processor for specialty processes, with a contractual document (purchase order or statement of work [SOW]) as the governance vehicle for communicating expectations of control of process changes. The supplier may elect to implement a standard as defined by an outside organization (e.g., AS 9145, *Requirements for Advanced Product Quality Planning and Production Part Approval Process from International Aerospace Quality Group*) or develop an internal method for control such as a Process Change Notification (PCN) system and flow that to an outside processor. In either case, the supplier must communicate the expectations to the outside processor and must develop the method for responding to the processor's notifications of a process change, such as providing process or product subject matter experts (SMEs) as needed to review a proposed process change.

In-house example: An in-house Process Center of Excellence is established where the governance documents are the supplier's own procedures and policies. If prior notification of a process change has been established as a customer (i.e., program) requirement, the process owner must be made aware of this requirement. Moreover, the in-house processor needs to establish communication with technical stakeholders outside the Process Center of Excellence to assess the risk of unintended consequences, and to use SMEs (both internal and customer-provided) to develop mitigations, such as screening tests, as deemed necessary to manage program risk. This becomes more difficult when the process provides product to several programs that may have unique product requirements that could be impacted in different and unique ways.

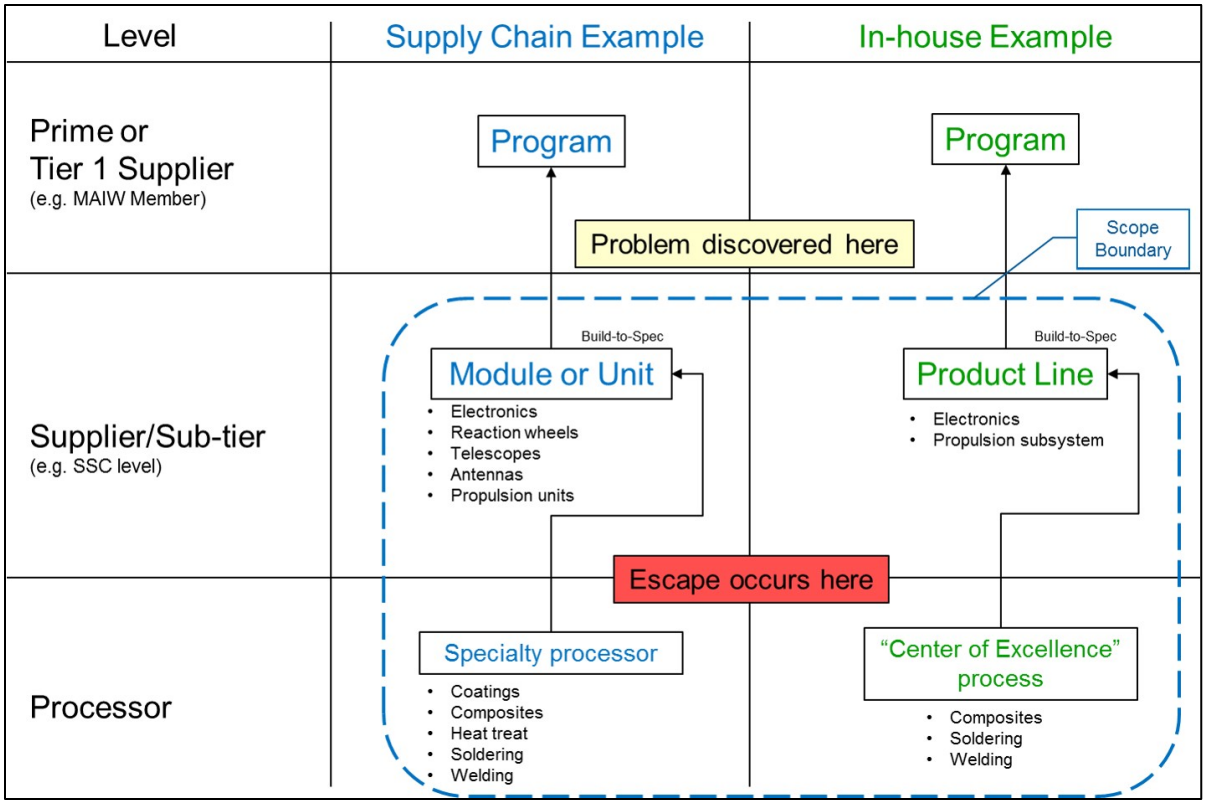


Figure 1. Process escapes at lower levels may not be discovered until higher levels of product integration.

Process changes may happen at outside specialty processors (Supply Chain Example in Figure 1) or at in-house Process Centers of Excellence (In-house Example in Figure 1). Problems occur when these changes manifest as unintended consequences at higher module- or unit-level builds, risking mission success.

1.2 Intended Users

The recommendations in this report are intended to be applicable at all levels of the manufacturing process from the prime customer to any processor that supports a sub-tier supplier.

The **prime customer** (Tier 1 in Figure 1) or end user will find guidance on the need to flow PCN requirements setting clear expectations to the contractor stating what is expected to control process changes before they take place. The primes will be able to set requirements identifying which subsystems or modules are critical and would be appropriate candidates for prior approval of process changes by the contractor. The primes will also be able to identify which PCN methodologies and what best practice language would be appropriately applied to which contractors. The primes are required to fully explain the end uses and criticality of the module or system involved (when possible and not restricted by International Traffic in Arms Regulations [ITAR], security classification, or other similar restriction).

At the **supplier/sub-tier contractor** (Tier 2 in Figure 1) level, this report will direct the suppliers—through their program management, procurement, technical disciplines, and mission assurance—to review and consider PCN requirements that are flowed to them by prime customers. Suppliers will be able to identify what tools are commonly used to assess any potential process changes. Suppliers will also be able to select the critical processes both in-house and at the sub-suppliers that support the appropriate end-use risk mitigations. In addition, suppliers will find the best practice language to guide both their in-

house process centers and those at the sub-tier suppliers. Finally, suppliers will be able to identify when to involve the primes in a change decision to understand the "propagation effects" of process changes.

Similarly, at the **processor** (Tier 3 in Figure 1) level, this report will inform manufacturing of the need to control seemingly innocuous process changes and the opportunities for unintended ramifications of their process changes. This report provides questions to aid in identifying "improvements" that can have unintended consequences.

Finally, professional associations or educational organizations can use this product to reach target audiences and memberships who may be involved in establishing process change controls. Professional organizations such as the American Institute of Aeronautics and Astronautics (AIAA), IPC – Association Connecting Electronics Industries (IPC), the International Aerospace Quality Group (IAQG), the Joint Electron Devices Engineering Council (JEDEC), the National Aerospace and Defense Contractors Accreditation Program (Nadcap), the Society for the Advancement of Material and Process Engineering (SAMPE), and others can be instrumental in building awareness and informing the general space community of the benefit and approaches of mitigating the risks of process changes, as well as benchmarking the most useful tools and policies currently in use.

2. Applicable Documents and Common Process Change Terminology

There is a wealth of higher-level documentation (see Table 1) in the space industry that provides general guidance on how to manage "classical" engineering. However, even with this documentation, some failures related to process changes have escaped the normal screening techniques. Additional guidance documents outside the space industry were reviewed to assess different types of process controls. Section 4 and Appendix A summarize the findings.

Table 1. Applicable Documents

Document Number	Document Title	Scope
AIAA S-102.2.4-2015	Capability-Based Product Failure Mode Effects and Criticality Analysis (FMECA) Requirements	Establishes uniform requirements and criteria for a capability-based FMECA which is a useful tool to understand the risks associated with a process change.
AS9145 (TBD)	Production Part Approval Process (PPAP) is a Process Failure Modes and Effects Analysis (PFMEA)	The PFMEA systematically reviews each step of a process—or a *change* in an existing process—and identifies all potential failure modes and what effect(s) might result. See Section 6.6 for additional discussion.
MDA-QS-001-MAP	Missile Defense Agency Assurance Provisions (MAP)	A set of safety, quality, and mission assurance requirements for mission- and safety-critical items; includes requirements for reporting Class I and Class II changes.
SAE J 1739:2009	Potential Failure Modes and Effects Analysis in Design (Design FMEA), Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)	An analytical methodology used to assess the risks of potential failure and ensure that potential problems have been considered and addressed. Documents the collective knowledge of a set of cross-functional SMEs.
TOR-2008(8506)-8377	Guideline for Space System Late Changes Verification Management	Addresses recommended processes to minimize overlooked requirement changes resulting from "late changes." Does not specifically address unintended consequences from innocuous/Class II changes.
TOR-2011(8951)-19	Failure Review Board Guidance Document	Guidelines for failure review board (FRB) requirements, organization, process, and interface.
TOR-2012(8960)-5	Guidance for Efficient Resolution of Post-Contract Award Mission Assurance (MA) Requirement Issues	General guidance and recommendations in support of MA; includes a comprehensive appendix of relevant documents for material review boards (MRBs); FRBs; ERBs; parts, materials, and processes control boards (PMPCBs); and change control boards (CCBs).
TOR-2015-01904	Tailoring of EIA-649-1: Definition of Major (Class I) Engineering Change Proposal	Defines Class I and Class II engineering changes in contractual terms for program applicability (SHALL, WILL, etc.).
TR-RS-2007-00013	Reliability Program for Space Systems	Guidance on process controls for critical items.
TR-RS-2013-00001	Systems Engineering Requirements and Products	Information on ERBs, CCBs, and potential effective venues to review proposed process changes.
TR-RS-2013-00009	Parts, Materials and Processes Control Program for Space Vehicles	Definitions and recommendations for implementation of a program PMPCB.
TR-RS-2014-00003	Quality Space and Launch Requirements Addendum to AS9100C	Addendum intended to address best space industries practices missing from AS9100.

Table 2 provides a list of common definitions used in this document. These definitions are intended to provide a basis for a common understanding and use of terms across U.S. space programs. Many of the definitions are taken from the IAQG dictionary [1], MIL-STD-1540 [2], TOR-2011(8591)-18 [3], and TOR-2011(8591)-19 [4].

Table 2. Common Process Change Terminology

Term	Definition
Anomaly	Any deviation from expected performance associated with remotely operated element(s). Anomalies (and faults) can include hardware failures, recoverable hardware upsets, or infrequent extreme.
Assembly	A collection of sub-assemblies to form a configured item for installation onto the space vehicle.
Audit	A systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Capable	A process is capable when it is repeatable and produces the desired output within the expected cost constraints. Capability refers to the ability of a process to fulfill requirements for a product. In addition, this term as used herein includes the throughput required to prevent gridlock at the inspection process.
Class A	A Class A space vehicle is an operational asset. It is the lowest risk (meaning all practical measures are taken to reduce risk) space vehicle that is of the highest importance to national security with the highest confidence of success (the highest procurement and assurance standards are used) and the required long on-orbit life for a given orbit. Class A is reserved for space vehicles for which mission failure results in: • an unacceptable collection gap, an unacceptable delay of a new capability, or an unacceptable reduction of capabilities • a potential human safety hazard • a security breach
Class B	A Class B space vehicle may be an operational asset. It is a low risk (meaning most practical measures are taken to reduce risk) space vehicle that is of high importance to national security or safety (such as a high impact weather satellite) with high confidence of success (the highest procurement and assurance standards are used) and the required moderate to long on-orbit life for a given orbit. Class B represents the best industry standards for a high reliability, high quality, and long design life space vehicle.
Class C	A Class C space vehicle is not an operational asset. It is a demonstration space vehicle. Demonstration space vehicles generally utilize new technologies to demonstrate new space vehicle capabilities. Class C space vehicles are moderate risk with some application to national security, moderate confidence of success, and the required short to moderate on-orbit life for a given orbit.
Class D	A Class D space vehicle is not an operational asset. It is a proof-of-concept or fast-turnaround space vehicle. Proof-of-concept and fast-turnaround space vehicles generally are used to test new concepts or provide a high-risk immediate capability in space. Class D space vehicles are high risk with little to no application to national security, low confidence of success, and the required short on-orbit life for a given orbit.
Critical process	A process for which failure or likelihood of failure would seriously endanger the safety of personnel or alternatively, produce product that could seriously degrade a mission or result in mission failure.
Customer	The purchasing organization, often the U.S. government, who initiates the contract with the prime.
Defect	Nonfulfillment of a requirement related to an intended or specified use.
Engineering review board (ERB)	A cross-functional team that analyzes proposed engineering changes for approval or rejection.
Escape	An inspection error as evidenced by an issue found at a higher level when it should have been caught at the first opportunity presented to inspection.
Failure	Termination of the ability of an item to perform a required function. Note: • After failure, the item has a fault. • This concept as defined does not apply to items consisting of software only.

Term	Definition
Failure, Modes, and Effects Analysis (FMEA)	A process for analysis of potential failure modes within a system for classification by severity or determination of the effect of failures on the system.
Failure review board (FRB)	A group, led by senior personnel, with authority to formally review and direct the course of a root cause investigation and the associated actions that address the failed system.
First article	First article includes production models, initial production samples, test samples, and pilot model. Approval of the first article involves testing and evaluating the first article for conformance with requirements.
Fishbone diagram	Also called a cause-and-effect diagram or Ishikawa diagram, a fishbone diagram is a visualization tool for categorizing the potential causes of a problem in order to identify its root causes.
Human factors	The study of how humans behave physically and psychologically in relation to particular environments, products, or services, and the potential effect on safety. Recognition that personnel performing tasks are affected by physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication, and attitude in order to ensure a safe interface between the personnel and all other environmental elements such as other personnel, equipment, facilities, procedures, and data.
In-house	Done or existing within an organization (internally), or without assistance from outside the organization.
Lessons learned	A lesson learned is knowledge or understanding gained by experience that has a significant impact for an organization. The experience may be either positive or negative. Successes are also sources of lessons learned.
Likelihood	The chance that something might happen. Likelihood can be defined, determined, or measured objectively or subjectively, and can be expressed either qualitatively or quantitatively.
Manufacturing readiness review (MRR)	Determines the readiness of the manufacturer to proceed with manufacturing of the product. This event is sometimes referred to as a build readiness review (BRR) or production readiness review (PRR). The software architecture readiness review is analogous to the MRR and is conducted at the completion of the software development planning and architecture definition.
Material review board (MRB)	The MRB typically consists of individuals trained and certified to the MRB process. This is a cross-functional group that normally reviews nonconforming materials, assemblies, or procured items prior to acceptance or system integration. The MRB can alert the FRB that anomalies that may require FRB attention have occurred. Subsequently, the MRB performs associated failure analysis and/or regression activities with FRB oversight. The MRB process includes the nonconformance database used to track and close the system or component anomalies.
Method	Practice, procedure, method, and work instruction are named in accordance with the nomenclature of business command media and share the following definition: A document that defines what processes must be performed, what products must be produced, when and how often it must be done, and who is responsible. It may also include the "How to" instructions that implement the process.
Methodology	The systematic, theoretical analysis of the methods applied to a field of study. It comprises the theoretical analysis of the body of methods and principles associated with a branch of knowledge.
Mission assurance (MA)	The disciplined application of general systems engineering, quality, and management principles that provides confidence towards the goal of achieving mission success. MA focuses on the detailed engineering of the acquired system, and toward this objective, uses independent technical assessments as a cornerstone throughout the entire concept and requirements definition, design, development, production, test, deployment, and operations phases. [5]

Term	Definition
Nonconformance	1. A condition of any article, material, or service in which one or more characteristics do not conform to requirements specified in the contract, drawings, specifications, or other approved product description. Includes failures, discrepancies, defects, anomalies, and malfunctions. 2. Parts or materials that do not meet specifications or requirements. The failure of a characteristic to conform to the requirements specified in the contract, drawings, specifications, or other approved product description.
Parts, materials, and processes control board (PMPCB)	The PMPCB is a formal contractor organization established by contract to manage and control the selection, application, procurement, qualification, and inspection of parts, materials, and processes used in equipment supplied to the standard SMC-S-009 [6].
Prime	The organization that is the lead integrator for an item or service and has the responsibility for delivery of that item or service.
Prime contractor/ Tier 1	Physical or moral person or organization which is responsible to the customer and, within the framework of a contract, responsible for carrying out a complex whole, which may necessitate participation of several suppliers.
Printed wiring board (PWB)	The circuit board used to mount components and create circuits.
Process	1. A combination of people, material, machines, tools, environment, and methods that produce a product or service. 2. Set of interrelated or interacting activities which transforms inputs into outputs. Notes: • Inputs to a process are generally outputs of other processes. • Processes in an organization are generally planned and carried out under controlled conditions to add value. • A process where the conformity of the resulting product cannot be readily or economically verified is frequently referred to as a special process.
Process changes	(For the purpose of this report) Processes that are directly associated with the building of hardware.
Process control	A process is under control if it is repeatable, stable, and operating at its designed target with normal variation.
Process failure modes and effects analysis (PFMEA)	PFMEA is a structured approach to preventive action that assigns a risk priority number (RPN) to each process step based anticipated failures. The RPN is the product of frequency of occurrence, severity, and detection.
Processor/Tier 3	Supplier that supports and provides material to a sub-tier supplier.
Program	1. Projects managed in a coordinated way to obtain benefits not available from managing them individually. 2. A coordinated set of technical, administrative, and financial tasks aimed to satisfy contract needs. Note: • This could cover any combination of design, development, production, usage or support.
Qualification	A sequence of tests, analyses, and inspections conducted to demonstrate satisfaction of design requirements including margin and product robustness for designs [2].
Quality assurance provision (QAP)	A QAP is documented inspection criteria used to assess conformance to drawing requirements. It is part of the technical data package (TDP) and contains reference documents, classification of characteristics, sampling criteria, inspection methods, certification requirements, test methods, and procedures. Often referred to as a Q-note.

Term	Definition
Reliability	1. The probability of failure-free operation of a computer program in a specified environment for a specified time [7]. Note that software reliability requirements should consider the level and manner of fault and failure detection, isolation, fault tolerance, and recovery expected to be fulfilled by the software. 2. Ability of an item to perform a required function under given conditions for a given time interval. Notes: • It is generally assumed that the item is in a state to perform this required function at the beginning of the time interval. • Generally, reliability performance is quantified using appropriate measures. In some applications, these measures include an expression of reliability performance as a probability, which is also called reliability.
Requirement	Need or expectation that is stated, generally implied, or obligatory.
Root cause corrective action (RCCA)	Root cause is the identification of the failure from which a chain of effects or other failures originates. Corrective action is the activity undertaken to eliminate the cause of a detected nonconformity. RCCA efforts are usually deployed on situations of a serious nature.
Stakeholder	A person or group that has an interest or actionable responsibility in the outcome.
Statement of work (SOW)	A SOW is a document routinely employed in the field of project management. It defines project-specific activities, deliverables, and timelines for a vendor providing services to the client.
Sub	The organization that is producing an item or providing a service for a prime.
Sub-tier Supplier/ Tier 2	1. Supplier not working under a direct purchase order from the prime contractor but performing work on related products at a lower level in the supply chain (via purchase order cascade). 2. All organizations that are tasked by a supplier to perform a portion of the required effort in the contract between the prime and the supplier.
Subcontractor	Supplier or other organization that enters into a subcontract with the primary contractor and assumes some of the obligations of the primary contractor.
Supplier	1. The furnisher of articles or related services, at any tier, to an approved manufacturer. 2. An organization that enters into a contract with the acquirer for the supply of a system, software product, or software service under the terms of the contract. The term supplier is synonymous with contractor, producer, seller, or vendor. 3. The entity or party that supplies product or services to a customer per the contract. 4. Reference ISO 9000 terms and definitions. 5. Organization or person that provides a product. Examples of a supplier are producer, distributor, retailer, or vendor of a product or provider of a service or information. Notes: • A supplier can be internal or external to the organization. • In a contractual situation, a supplier is sometimes called “contractor”.
Supply chain	Network created by customer, prime contractor, subcontractors, and sub-tier suppliers producing, handling, and/or distributing a specific product.
System	1. A collection of related processes and tools. 2. A set of interrelated or interacting elements. Note: The system is considered to be separated from the environment and other external systems by an imaginary surface which cuts the links between them and the considered system. Through these links, the system is affected by the environment, is acted upon by external systems, or acts itself on the environment or the external systems.

Term	Definition
Test readiness review (TRR)	TRR verifies that the program is ready to proceed with the formal testing and is typically held as a series of events prior to each round of testing, such as baseline integrated system test (BIST). Each software build product delivered to either internal or external users has a separate TRR.
Testing	A measurement used as a means of determining if functional requirements of a product are met.
Tool	Hardware or software that automates some portion of product or process implementation.
Units	A functional item that is viewed as a complete and separate entity for purposes of manufacturing, maintenance, or record-keeping. The analogous term for software is computer software unit (CSU) and typically is a well-defined function within a computer software configuration item (CSCI) (e.g., Kalman filter CSU within the navigation CSCI).
Verification	Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

3. Process Change Assessment

This process change assessment analyzed data from various sources for process changes that created hardware failures at subsequent levels of assembly, integration, test, or customer use. Twenty-two examples were analyzed and are summarized in Table 4. Each escape was assigned to a potential cause on a fishbone. Potential causes were ranked and the top three investigated further.

3.1 Survey and Root Cause Analysis

The team surveyed data from various sources (lessons learned and root cause corrective action [RCCA] databases, FRB, MRB, etc.) for "changes" in manufacturing processes that created hardware (HW) failures or negative consequences at subsequent levels of assembly, integration, test, or customer use. The intent was to look for failures that were attributed to seemingly inconsequential or innocuous process changes (procedure, tooling, process improvement, supplier changes, materials changes, etc.) directly linked to the failure of the assembly or system.

3.1.1 Data Sources

Data primarily came from items captured by contractor failure review and corrective actions systems. The issues affected both military and commercial programs, and are believed to have occurred within the last 20 years. Table 4 is a summary of findings.

3.1.2 Collection Criteria

Over 30 escapes were evaluated using the criteria in Table 3. Some were eliminated because they were found to be product changes rather than process changes, while others were eliminated because either too little information was provided to ascertain what type of escape they were or they failed to point adequately to a root cause. The remaining 22 escapes listed in Table 4 were evaluated and appeared to naturally associate into data collection criteria for process change escape types.

Table 3. Escape Evaluation Criteria

Characteristic	Criteria for Collection
Manufacturing process and material related	Lower assembly-level manufacturing that was performed by sub-tier suppliers or within contractor manufacturing centers that may have had process or material changes with no perceived effect at the manufacturing level, but that caused failures at a higher assembly levels or on orbit.
Intended changes	The process changes made were intentional and were made for improvements, streamlining, cost cutting, or other beneficial purposes.
Seemingly innocuous	The changes made seemed sound and were perceived as little or no risk for degraded performance or failure at high levels of integration.
High-impact consequences	When a failure or escape was finally realized, it caused high expenses, significant schedule delays, or on-orbit performance degradation.

Table 4. Summary of Escapes

Item	Change Type	Issue	Level of Impact	Potential Causes
1	Tooling	After delivery to the customer, it was determined that a bank of capacitors laminated to a heatsink in the assembly had the potential to delaminate during customer use. A tooling change was made in the lamination process as an improvement. The fixture went from individual pressure plates that apply pressure to each individual capacitor to a single pressure plate that covered the entire capacitor bank. The change did not account for variation in capacitor height which prevented the shorter caps from receiving the right amount of pressure to properly laminate to the heatsink.	Unit level	• Poor flow-down of requirements and applications knowledge • Failure to accurately assess severity
2	Testing	Top-level assembly failures were occurring during environmental stress screening (ESS) testing. A sub-tier supplier implemented a “wiggle” test to screen for via failures on a printed wiring board (PWB) during the manufacturing test process. The wiggle test induced mechanical stress to an adjacent capacitor, causing fracture of the cap termination and latent failures that exhibited during ESS at the top-level assembly.	Program level	• Failure to accurately assess potential failure modes • Too much work • Failure to accurately assess severity
3	Part	A sub-tier supplier made an improvement that removed the anti-reflective coating from the optical fiber subassembly used in a hybrid. During cycling overextended temperature at the sub-tier supplier, an adhesive cracked, which resulted in misalignment of the optical path. Failure analysis determined removing the anti-reflective coating caused a decrease in bond strength between the optical prism and fiber subassembly. The change resulted in a recall of affected HW.	Below unit level	• Failure to accurately assess potential failure modes • Not a real change (improvement)
4	Supplier	A sub-tier attenuator supplier used a different plating processor for internal connector pins. Inadequate cleaning of plating residue resulted in poor electrical contact at cold temperatures and resultant high loss at radio frequencies (RFs). There was an impact across multiple programs and contractors, and in one case, the program had to remove and replace (R&R) hundreds of attenuators after vehicle integration.	Program level	• No stated requirement to notify customer • Failure to verify flow-down to sub-tier suppliers
5	Testing	Reach-back assessments were required on an imminent government satellite launch and there was impact across multiple programs and contractors. A hybrid assembly supplier upgraded the hybrid device test rack and software. The new software test routines did not perform a safety check prior to the application of voltages, resulting in damage or potential overstress to flight hybrids.	Program level	• Poor flow-down of requirements and applications knowledge • Not a real change (improvement)
6	Part Process	The premature failure of primary reaction wheel assemblies (RWAs) on orbit necessitated a switch to redundant RWAs. There were multiple “minor” changes to ball bearings, lubricants, cleaning procedures, and other processes used in RWAs, but the suppliers were unable to perform complete test-like-you-fly (TLYF) or accelerated life testing prior to program launch needs.	On-orbit	• No ability to test process change

Item	Change Type	Issue	Level of Impact	Potential Causes
7	Material	A rocket nozzle failure during test firing was due to delamination of a replacement insulator. A sub-supplier problem prompted the supplier to select a replacement resin for the nozzle skirt. The new material met the applicable specification, had been used on other programs, and had passed an array of tests in the laboratory. However, test results of the new material were statistically different from the original material, and test conditions were not sufficiently flight-like. Many of the material properties were measured at room temperature, whereas the flight temperature approached 3000°F. Additionally, certain critical properties were not measured, and the vital thermal expansion test was performed at too low a heating rate.	Unit level	• Inadequate test for process change
8	Material	The propulsion valves in a rocket broke down just before launch because the oxidizer reacted unexpectedly with a new cleaning solvent.	Launch	• Failure to accurately assess potential failure modes • Failure to go far enough up the customer chain • Inadequate review board
9	Material	A satellite fired its attitude-control thrusters too often, depleting its fuel. The failure was traced to the propellant tank, which developed a dipole moment that torqued the satellite to align with the Earth's magnetic axis, overtaxing the thrusters. The tank was supposed to be made of titanium, but a switch to stainless steel was made due to schedule deadlines. Annealed stainless steel is normally nonmagnetic, but the metal possibly became magnetized either while being worked into the hemispheric shape, or when it was exposed to an external magnetic field. Unfortunately, the possibility of magnetization did not occur to anybody, otherwise a simple degaussing would have averted the failure.	On-orbit	• Poor flow-down of requirements and applications knowledge • Inadequate review board
10	Facility Change or Building Modification	Glass/ceramic body fuses were discovered to be defective after installation on circuit card assemblies (CCAs). A program discovered that the fuses failed high-resistance in-circuit probe testing. Destructive physical analysis (DPA) determined that the cause of the failures was poor solder wetting of the filaments at the endcaps. The supplier had moved their manufacturing from the U.S. to the Philippines without properly validating soldering temperature and dwell time at the new facility.	Unit level	• Poor flow-down of requirements and applications knowledge • No stated requirement to notify customer • Too much work
11	Material	As a producibility improvement, a change was made to the surface finish of a propulsion device. Early in life testing, intended to demonstrate mission life, the unit generated higher temperatures than expected. The life test was halted and use of the old surface finish was reinstated.	Unit level	• Failure to accurately assess potential failure modes

Item	Change Type	Issue	Level of Impact	Potential Causes
12	Material	During lot-acceptance testing, the leak detector samples failed to provide positive indication during and following exposure to the target gas. The leak detector is fabricated by treating an indicating card with chemicals that change color when exposed to the gas (similar to pH-sensitive litmus paper). The investigation found part of the failure was due to an unexpected change in the type of paper stock used. It was more difficult to reliably apply the detection compound to the new thicker-stock material, which was impregnated with another chemical which worked to defeat the detection reaction.	Parts level	• Not a real change (improvement)
13	Manufacturing/ Assembly Process	A program was experiencing repeated bond wire failures in a miniature opto-coupler within the latest batch of power hybrid assemblies. The investigation found that the sub-tier supplier had implemented a special change to their molding process at the request of the hybrid manufacturer. The request was intended to increase the gold pad area and ease the attachment process for the next-level hybrid assembly, but resulted in the bond wires being entrapped in the epoxy over-coating, resulting in stress fractures during thermal cycling.	Program level	• Failure to accurately assess potential failure modes
14	Material	During installation, the body of shock isolators cracked during torqueing. The mechanical shock isolator material had been changed from extruded aluminum to cast aluminum, and the part number was not changed to reflect the new material process. The new material had inherent casting defects which failed during application of torque. Additional inspections of loose stock and fielded units were required.	Unspecified	• Inadequate test for process change • Not a real change (improvement)
15	Supplier	Travelling wave tube amplifiers (TWTAs) had a failure during thermal vacuum testing in an epoxy-encapsulated Zener diode with high leakage current. The root cause was due to a change from one diode sub-tier supplier to another. The newer diode was mechanically weaker and less resistant to thermally induced stresses. Module-level screening was performed at lower temperature ranges than those used at unit level.	Unit level	• Poor flow-down of requirements and applications knowledge
16	Process Variation	There were recurring incidences of copper plating delamination and tuning screw solder reflows in sub-tier supplier diplexers. The underlying causes were manufacturing process variations at the processor. The processor updated manufacturing instructions with detailed specifications and inspection points to eliminate process variations. The processor also incorporated modernized equipment to improve contamination control during the plating process.	Unit level	• Inadequate test for process change
17	Supplier	A disruption of production and some penalty testing was incurred due to a change not properly communicated by a diode supplier. Diodes had been soldered in-house using a low-temperature hand-soldering process. This process step was sublet to a third-party soldering service that subsequently changed to a reflow solder process instead of low-temperature hand solder. The change was communicated after the fact by e-mail.	Below unit level	• Not a real change (improvement)

Item	Change Type	Issue	Level of Impact	Potential Causes
18	Process Design	The manufacturer of a crystal oscillator changed the design and fabrication processes without adequate testing and screening under all possible operating conditions. The defective oscillators passed limited piece-part factory automated testing, but failed to perform as needed after integration into higher-level products.	Unit level	• Failure to accurately assess potential failure modes • Inadequate test for process change
19	Facility Change or Building Modification	A disruption of production and some penalty testing was incurred due to a coupler supplier changing location without notifying its customers. The couplers were manufactured at a location on the East Coast, but moved to a location in another state because of Hurricane Sandy.	Below unit level	• Failure to go far enough up the customer chain
20	Tooling	A disruption of production and some penalty testing was incurred due to nonconforming components being shipped from a ball grid array (BGA) supplier. The BGA supplier changed the method of inspection for co-planarity. A legacy inspection tool failed and another piece of inspection equipment was introduced to maintain throughput. The replacement inspection equipment was not calibrated to accurately measure compliance for co-planarity.	Below unit level	• Inadequate test for process change • Failure to go far enough up the customer chain
21	Manufacturing/ Assembly Process	Performance degradation of monolithic microwave integrated circuits (MMICs) caused a disruption in production at the higher unit level. The sub-tier wafer supplier of the MMICs changed a critical process without notifying its customers. The change was intended to improve fabrication processing efficiency.	Below unit level	• Inadequate test for process change • Failure to go far enough up the customer chain
22	Facility Change or Building Modification	Charge coupled device (CCD) yield declined at a sub-tier supplier manufacturing facility due to contamination that was identified as “fibers.” The cause was traced to a building modification that was made in order to reduce the risk of electro-static discharge (ESD) failures. Evaporative coolers were installed to keep the relative humidity (RH) above 30 percent, but the coolers turned out to be the source of the “fibers.”	Below unit level	• Failure to accurately assess potential failure modes

3.2 Potential Causes

An Ishikawa-style fishbone diagram, shown in Figure 2, was generated to identify potential causes for why the customer was not notified prior to the change. The individual escapes were each assigned a potential cause. In the cases where the set of information was incomplete, the root cause was made from an extrapolation of the available information. Assumptions were made where the complete reasoning behind the process change was not clear. The potential causes were ranked as shown in Figure 3, and the top three were investigated further.

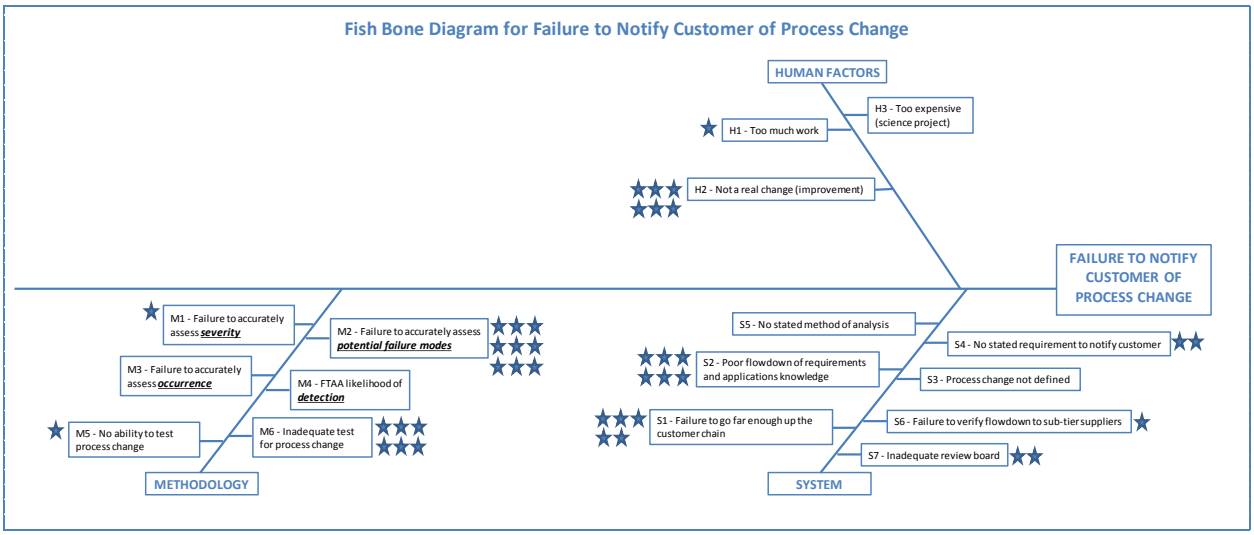
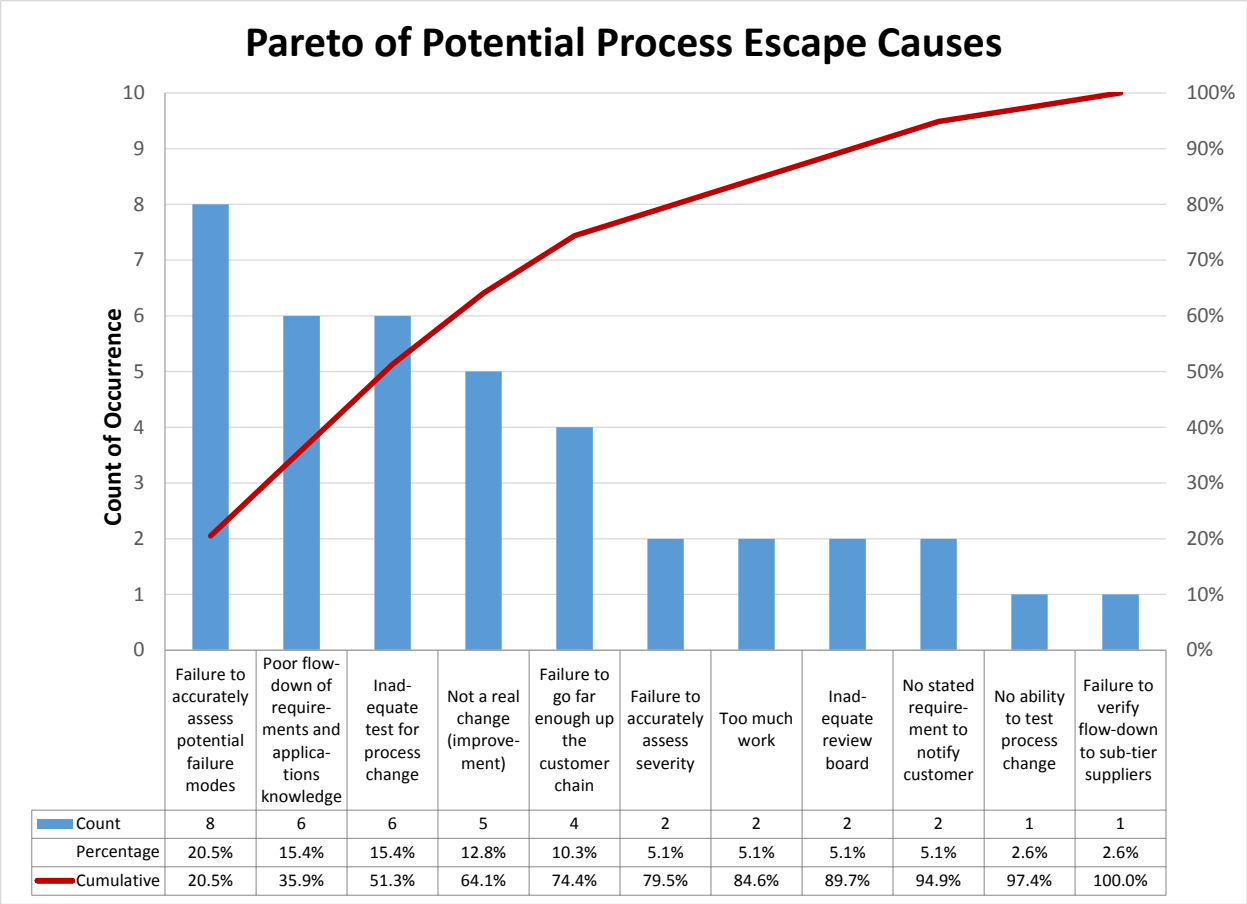


Figure 2. Fishbone for failure to notify customer.



	Failure to accurately assess potential failure modes	Poor flow-down of require-ments and applica-tions knowledge	Inad-equate test for process change	Not a real change (improve-ment)	Failure to go far enough up the customer chain	Failure to accurately assess severity	Too much work	Inad-equate review board	No stated require-ment to notify customer	No ability to test process change	Failure to verify flow-down to sub-tier suppliers
Count	8	6	6	5	4	2	2	2	2	1	1
Percentage	20.5%	15.4%	15.4%	12.8%	10.3%	5.1%	5.1%	5.1%	5.1%	2.6%	2.6%
Cumulative	20.5%	35.9%	51.3%	64.1%	74.4%	79.5%	84.6%	89.7%	94.9%	97.4%	100.0%

Figure 3. Pareto of potential process escape causes.

Based on the experience of the team members and the available data from the individual escapes, it is believed the change(s) was/were known and made intentionally. The escape manifested itself as a result of "someone," an organization, or a customer who:

- Did not believe change was an impact (innocuous change)
  - Prime or supplier did not provide adequate technical requirements permitting the sub-tier or processor to change material type and no subsequent change analysis was performed.
  - Supplier facility move and lack of subsequent process verification allowed for various improper process application(s). Customer did not require nor perform a change analysis (i.e., requalification).
- Believed a subsequent screen would detect any nonconforming condition
  - Customer or supplier was aware of process change but did not have enough information to properly assess whether its current screening techniques would be perceptive to all nonconforming conditions.
- Did not have a clear understanding of the application (use) requirements

- Process changes were made but there was a lack of "effective" change notification. The supplier did not adequately perform a detail impact analysis of the change, resulting in a higher level of integration failure.

3.2.1 Analysis of Process Changes

Figure 4 shows the process change types of the escapes analyzed where the change was clearly identified. Sixteen of the twenty-two escapes were attributed directly to manufacturing processes, materials, or facility changes. The others spanned testing, supporting tooling, parts, or facility environment changes. Unknown change types were excluded from the chart.

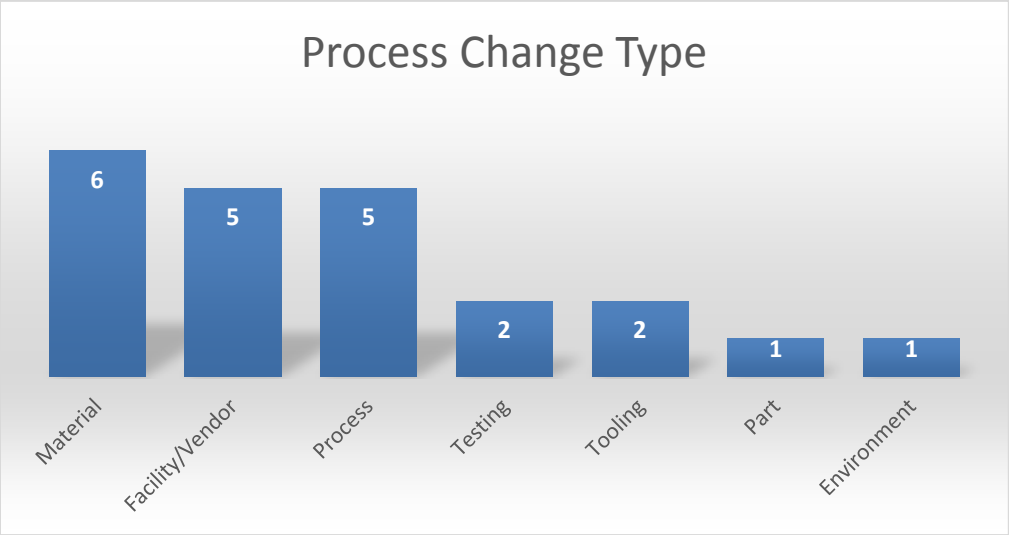


Figure 4. Manufacturing process and material related.

Figure 5 shows where in the manufacturing flow escapes had an impact. More of the issues were caught at a lower level and fewer materialized at a higher level (further in the manufacturing flow). Those that emerged at a higher level had higher impact. Unknown levels of impact were excluded from the chart.

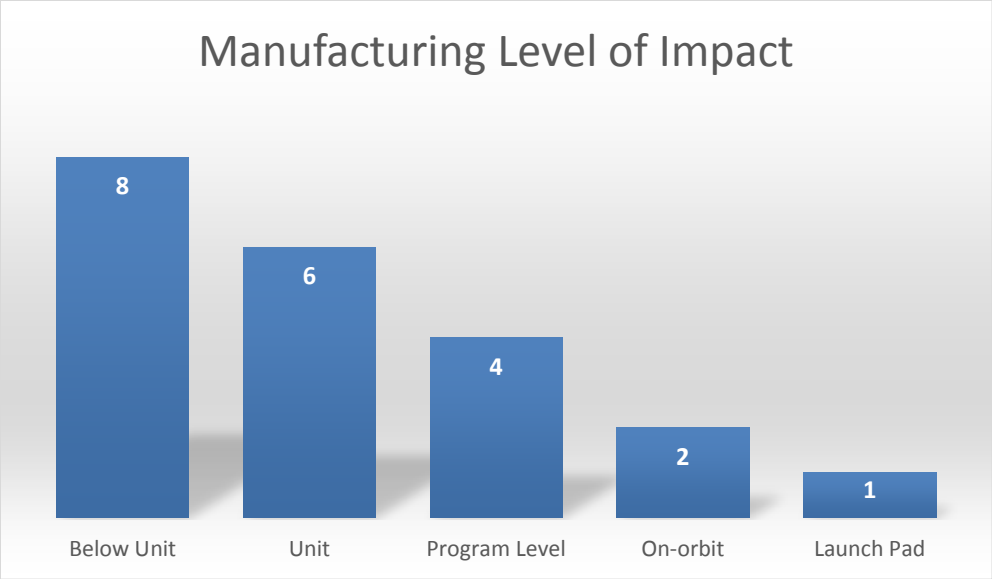


Figure 5. Manufacturing level of impact.

Figure 6 shows that the most common indications of an escape, or how the escape manifested, were failures in screening or qualification tests, including life test. The remaining escapes are of wide distribution without specific trend. Unknown indications were excluded from the chart.

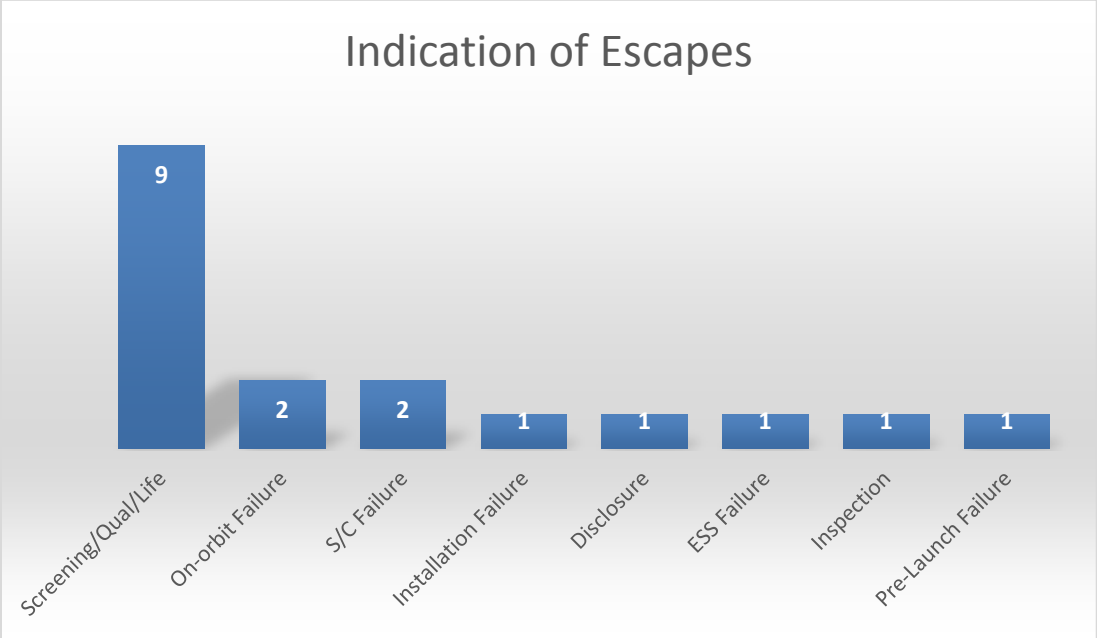


Figure 6. Indication of escapes.

The reasons behind why a change is made yield a wide and flat distribution without any specific trend. This shows a change can be made for a variety of reasons and does not make any difference why. Unknown reasons for change were excluded from the chart.

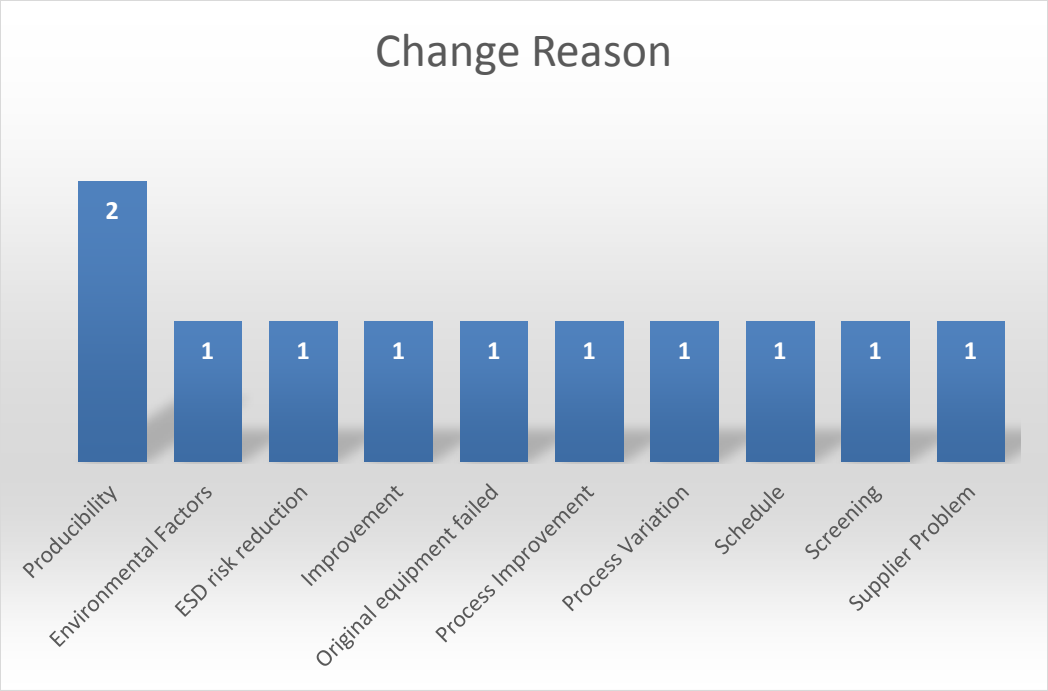


Figure 7. Change reason.

In performing data analysis for identified issues, the results suggested a number insights.

There were a low number of issues found that fit the collection criteria, even though there was an extensive industry-wide search conducted. Although the exact number is unknown, there were a great deal of candidate issues evaluated, out of which only the 22 issues met the criteria. The difficulty in finding a large number of issues points to an indication that high-impact, intended, seemingly innocuous process changes are not a widespread endemic problem. Rather, they appear to be black-swan events that are relatively rare, but have costly and memorable impacts. This suggests that industry practices and measures are generally effective, and that a generic, overbearing set of corrective actions may not be warranted or value-added. The conclusions and recommendations in this section are intended to provide additional insight and ideas to consider when faced with a process change.

Process change escapes found at lower-level manufacturing levels had lower cost and schedule impacts versus escapes at higher levels of manufacturing. This finding is not novel, but interesting in that it is consistent with trends for other types of failures.

The most common way these escapes were discovered were through screening and qualification testing at higher levels. Beyond this, the data shows a wide distribution for discovery without a trend. This suggests that improving screening effectiveness could help improve mitigation of these escapes.

The reasons that initiated the process changes that lead to escapes did not show a trend, which could be due to a lack of correlation between why a change was made and the ultimate result of that change. In other words, it does not appear that the reason a change was made had any impact on the probability of that change being a high-impact escape.

A process change map, or a notional flow of how an escape may occur, can be developed by reviewing all these examples and considering the potential causes. A failure at any of the steps on this map can result in an escape. Escapes can result if the processor is not aware that an action constitutes a change, if the

change is considered low risk, if the processor fails to perform an adequate risk analysis with the proper experts, or if the processor fails to implement an appropriate mitigation. This is illustrated in Figure 8.

Figure 8. Process change map.

In subsequent sections, this process change map can be used to clarify where process change mitigation tools and techniques might be applied to reduce the risk from process changes.

4. Benchmark Industries or Methods

A review of six trade associations was conducted to understand what policies or other pertinent guidelines each might have that could be used by its practitioners to manage and control process changes before a change was initiated or to assess the risk after an escape had occurred. The trade associations reviewed included:

- American Institute of Aeronautics and Astronautics (AIAA)
- IPC – Association Connecting Electronics Industries (IPC)
- International Aerospace Quality Group (IAQG)
- Joint Electron Devices Engineering Council (JEDEC)
- National Aerospace and Defense Contractors Accreditation Program (Nadcap, formerly NADCAP)
- Society of the Advancement of Material and Process Engineering (SAMPE)

These trade associations were selected because they comprise well-developed sources for procedural guidance for the design and manufacture of hardware used in space applications.

The purpose of the review was to identify tools that could be used to assess and then mitigate process change risks. The tool or technique should, at a minimum, provide methodologies to ensure that:

- potential problems that could result from a process change are identified
- an assessment of the risk for each potential problem would follow
- actions would be identified that mitigate the risk to an acceptable level for the program

After researching the available references from each of the trade associations, only one potential tool was found that was described in sufficient detail for consideration. All other process change guidelines were presented or discussed only at conceptual levels. As of this writing, the IAQG is in the process of releasing a standard—AS 9145, *Requirements for Advanced Product Quality Planning and Production Part Approval Process* [8]. In this guide, the IAQG refers to SAE J1739, *Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (PFMEA)* [9]. The procedure AS 9145 was slated for release in July 2016. The use of the PFMEA technique, when used with the correct team composition and applied prior to the execution of a process change, satisfies all the methodology criteria identified above and, when released, has the potential to become the most effective technique and methodology available. By identifying the PFMEA as an industry-appropriate tool that can be used to mitigate process change risks, IAQG provides the clear direction that the space systems industry appears to have been lacking.

A survey of process change techniques used by the Federal Drug Administration (FDA) for the medical industry—another industry where the risks associated with changes in manufacturing process can have high-risk, unwanted consequences—also yielded only higher-level discussions with no detailed guidance. The International Council on Systems Engineering (INCOSE) *Systems Engineering Handbook* [10] was also reviewed and although the handbook's section on configuration management contained good guidance on managing changes in general, there were no specific lower-level references for managing process changes. The team acknowledges that this trade association review was not exhaustive and that there may be detailed guidance on managing process changes to be found outside the seven resources listed in Table 5. The detailed summary and analysis of the materials and policies from each trade association is contained in Appendix A.

Table 5. Other Association Processes

	Trade Association	Process Change Governance/Processes
	American Institute of Aeronautics and Astronautics (AIAA)	ANSI/AIAA S-102.2.4-2015, *Capability-Based Product Failure Mode, Effects and Criticality Analysis*, discusses a structured process for conducting a product design review, but does not provide detailed direction to assess process changes.
	IPC – Association Connecting Electronics Industries (IPC)	IPC Handbook and J-STD-001 provide sample types of process changes (major versus minor), but stop short on providing specific methodology.
	Federal Drug Administration (FDA)	*Guidance for Industry, Q10 Pharmaceutical Quality System* recommends best practices based on ISO 9000 concepts, but no specific process change guidance.
	International Aerospace Quality Group (IAQG)	AS 9145, *Requirements for Advance Product Quality Planning and Production Part Approval Process*, and SAE J1739, *Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes*, are pending release July 2016.
	Joint Electron Devices Engineering Council (JEDEC)	JEDEC Standard 46C establishes procedures to notify customers of semiconductor product and process changes, but does not go beyond generic definitions of major and minor changes.
	Nadcap	eAuditNet is a web-based system by the Performance Review Institute to support the Nadcap auditing and accreditation system. It provides more of a checklist.
	Society of the Advancement of Material and Process Engineering (SAMPE)	SAMPE provides sponsors meetings and symposiums, but does not impose or recommend process change guidance.

5. Survey of Existing PCN and Control Requirements

The purpose of this section is to confirm existing controls so that guidelines herein for improving PCN do not duplicate or conflict with current industry best practices.

A survey was conducted of existing controls used by the companies of each topic team member. This survey assessed contractual controls (from customers to prime and from prime to suppliers), process change assessment techniques and inspection methods, and closed-loop failure reporting to provide reliable notification when a process escape was discovered. Additional information from prior technical operating reports (TORs) as well as current 2016 Mission Assurance Improvement Workshop (MAIW) products were considered (e.g., *Supply Chain Escapes Lessons Learned Handbook* [11]). The following sections provide further detail of the surveys.

5.1 Comparison of Existing Direction from Customers

Industry consistently uses contractual flowdown requirements to require customer notification/approval of certain types of engineering changes. After a review of industry requirements' documents, no specific reference to "process change" was found, while documents such as EIA-649-1 [12] emphasized "engineering change" with definitions of major and minor. The practices and templates recommended herein serve to minimize the risk of suppliers misdiagnosing what type of class change has occurred.

It is typical for customers to require approval of Class I engineering changes through contractual language regarding design authority and/or engineering control board. The intent is to ensure that changes affecting form-fit-function are supported by technical rationale and risk mitigation. Typical venues for reviewing and adjudicating Class I engineering changes are engineering change proposals (ECPs), PMPCB, design reviews, MRR, and TRR.

Customers are also typically involved in material and failure review boards (varying levels of customer insight-versus-authority, depending on the contract). Involvement and reporting of failures (major nonconformities, affecting form-fit-function) are often delineated by minor-versus-major, specifying a level of integration and/or test levels (e.g., subsystem acceptance testing) and timeliness of reporting. These involvements inform the customer of observed issues and nonconformities.

Government-Industry Data Exchange Program (GIDEP)/Space Quality Improvement Council (SQIC)/National Aeronautics and Space Administration (NASA) alert expectations are tailored by contract depending on the customer's affiliation with aforementioned organizations. The intent is to assess alerts for potential impact. Customers expect subcontractors to implement controls when alerts apply (e.g., lot date code and/or procurement limitations, scrap parts, etc.). When alerts apply, customer coordination is expected through the parts control board and/or material review board to ensure customer visibility/involvement.

5.2 Comparison of Existing Direction to Suppliers, Procurement Team

Companies implement quality provisions to subcontractors as described by their command media. The command media, in turn, describes the process and method by which the contractor flows down "notification" requirements to its subcontractors. Furthermore, in most cases the requirements often (and should) require the same requirements flowdown through the supply chain. The flowdown requirements should be contained in or be made part of the SOW and/or the purchase contract as part of the "Quality Assurance Provisions." The overarching goal is to flow down Class I change control and the level of MRB and FRB authority (depending on the mission risk posture) to suppliers. In some cases, companies further elaborate by defining what constitutes a process change (including definition of what types of

criteria correspond to a facility change). Additional best practices include quality assurance (QA) requirements specific to a type of commodity, material, and/or special process (e.g., ESD handling of CCD detectors).

Supplier mission assurance requirements or specifications are typically appended or embedded in the contract SOW. This levies expectations for supplier precap inspection, mandatory inspection points, MRB authority, and other quality requirements to minimize process escapes.

Process changes are typically controlled via the applicable quality assurance requirements that are found in the aforementioned documentation (either as a purchase order attachment or embedded as part of the SOW).

5.3 Existing Risk Assessment and/or Inspection Methods

Onsite supplier evaluations are usually coupled with special process questionnaires and supplier capability assessments. These techniques are used upfront by the procurement team to assess the ability and risk for the supplier to execute. During the performance of these evaluations, supplier process change definition, control, and customer notification processes should be reviewed to ensure compliance with the flowdown requirements. In addition, how the supplier flows down and provides the same level of control over their suppliers should be reviewed and understood.

Mandatory inspection points and source inspections are often imposed at predefined points in the manufacturing and test flow. Based on collective input from hardware quality engineers and supply chain quality engineers, the inherent value of source inspections is dependent on the level of visibility and time that the procurement/QA team has with the supplier, and the effectiveness often hinges on the quality of the relationships/partnerships themselves. An industry comparison of inspection checklists and protocols was considered beyond the scope of this document.

5.4 Assembly, Integration, and Test

The visibility of supplier anomalies depends on contractual requirements: what test phase, how MRB authority is defined, what anomaly/failure documentation is required, the timeliness of notification of an anomaly, and whether the anomaly is a major or minor nonconformity. Usually a database is maintained to record/report anomalies. It is common for suppliers to be required to notify procurement/QA teams when a nonconformity occurs after the start of acceptance testing of deliverable and/or flight hardware. For Class A missions (national assets), the level of reporting often begins prior to acceptance test (at first power application of deliverable hardware).

If a nonconformity/failure occurs after hardware is delivered, there is an investigation to determine root cause which includes, but is not limited to, whether the supplier was at fault or if there was a design escape, part failure, or perhaps a human error that caused the anomaly. This often entails a review of the process flow, whether any process changes were explicitly/implicitly made, and if there were any out-of-family indicators despite whether the end item met the performance specification.

In cases where deficiencies or escapes in a supplier process are identified, a supplier QA representative may coordinate a formal corrective action request with the supplier. There should be sustainment and verification methods to ensure the corrective action remains in place for future procurements.

5.5 Notable Discrepancies

After review of the current flowdown of requirements and subsequent processes for disposition of changes, there may be an opportunity to improve the requirements definition, flowdown, and notification "protocol" for process-related changes.

- Existing direction from Tier 1 and Tier 2 customers: Class I and II configuration management addresses engineering changes well; however, process changes are not explicitly addressed in industry requirements documents. Major and minor nonconformities are also typically defined well; however, they are not explicit in their differentiation of design versus process escapes.

- Existing direction to suppliers: The lack of consistent language in the "Quality Assurance Provisions (QAP)," including variability in what constitutes a process change (if defined at all), is an area for improvement. Of the companies surveyed, commodity or process-specific QAPs appeared to be used infrequently. There appears to be an opportunity to leverage tailored QAPs to a greater extent, perhaps in conjunction with when supplier process issues are discovered (whether by MRB, FRB, or supplier corrective action request (SCAR), etc.) to reduce likelihood of recurrence.

- Risk assessment and/or inspection methods: Special process questionnaires and process capability assessments typically were not tailored to program-unique requirements. In cases where these requirements are unfamiliar to the lower-tier supplier, a recommended area to focus on would be the tailoring of the questionnaire to help educate the supplier as to where there may be high sensitivity deltas/departures from the supplier's standard process.

- Assembly, integration, and test: There will always be an inherent dependency to be notified of supplier failures. The lower mission classes are more prone to escapes because of lesser failure reporting requirements at all levels. When process escapes occur, an area of opportunity is to focus (beyond the initial corrective action) on sustainment/verification.

6. Conclusions and Recommendations

6.1 Conclusion: The Data Set Underscored Several Recurring Root Causes

- There does not appear to be a comprehensive space industry approach to address process-related changes.
- Design-related changes are typically caught due to inherent detailed engineering review (ERB process).
- Evaluation of a change was not reviewed (or analyzed) by the appropriate disciplines.
- Commercial off-the-shelf (COTS) and components purchased from distributors need to be treated as a higher risk, as the ability to get process change information could be difficult.
- The majority of escapes occurred due to lack of communication between the change originator and higher-level users. This lack of communication increases the likelihood of a process escape.
- If the process change had been adequately communicated, additional perceptive screening could have been implemented or the change could have been prevented from occurring.
- No correlation was identified between why a change was made and the impact or severity of the change.
- Establishing effective testing is an important part of detecting a process change escape. However, relying on testing that lacks perception for the specific failure mode is a common reason why processors or suppliers see process changes as "innocuous" and do not pursue a more thorough inquiry of associated risks.

6.2 Conclusion: A Review of Trade Associations Did Not Find New or Previously Unknown Tools

- A review of trade association documents supports the use of the upcoming release of [8] containing a process-related failure modes and effects analysis as a thorough and risk-focused method to mitigate many of the process-related escapes.

6.3 Conclusion: A Review of Aerospace Industry-Related Documents Found Room for Improvement in Consistent Guidance

- There is not a common requirement to identify process changes as part of the requirements flowdown to suppliers.
- There is a lack of clarity in the flowdown requirements specifically addressing process-related changes, especially defining proof of change with results and justification.
- Supplier to prime communicated change is dispositioned. The adequacy of the evaluation to determine the appropriate disposition could not be determined.
- Current screening, inspection, and test performed at the piece part, module, units, subsystem, and end item deliverable are generally effective.

- When process change escapes do occur and result in identified product nonconformities, typically a detailed root cause investigation is conducted and lessons learned are incorporated.

6.4 Recommendation: A Common PCN Policy (Best Practices)

A common PCN policy across contractors would help address potential escapes by providing a checklist or standard that would encourage continuity of robust communications between all parties involved.

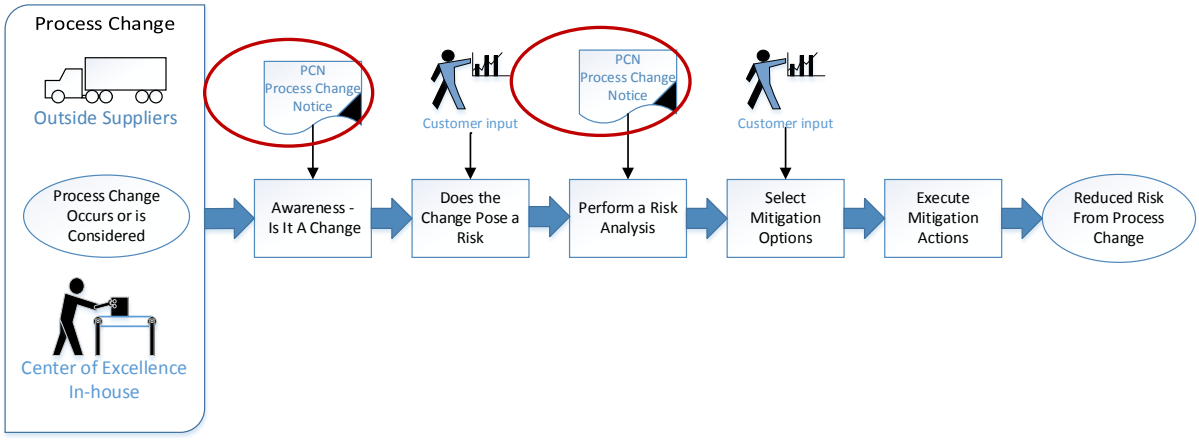


Figure 9. Common PCN—notification points.

A common PCN can guide a supplier or an internal processor to be able to answer "What constitutes a process change?" It can guide the determination of when a process change rises to the level of customer concern (risk analysis). It can also be a vehicle to invite the processor to determine when to get customer involvement. Together with appropriate customer involvement, mitigation options can be considered and executed.

6.4.1 Customer Input—Benchmarking a PCN Policy

A review of several companies' flowdown requirements for PCN was conducted and one was selected as a benchmark example. As a sample, within a proposed PCN policy, the procedure could state: "The supplier change management process mandates that suppliers provide 'prior notification' of changes in products and/or processes to the buyer and obtain customer approval before implementing a change. The customer is required to communicate the PCN requirement to suppliers through the application of a Supplier Change Request/Notification."

The benchmark policy provided contractual PCN guidance to key suppliers by the inclusion of a QAP, also called Q-note. The policy might have been improved by more precisely defining what constitutes a process change. The team would suggest the inclusion of the "process improvements (changes)" listed in Section 7.1. The policy also discusses the involvement of program and supplier quality in the review of the SCRN and the possible need for further actions such as conducting a new first article. Program quality would work with engineering to assess the need to develop a qualification plan and to assemble a cross-functional team to review the proposed change from suppliers.

6.4.2 Elements of a PCN Policy

- Define/engage appropriate stakeholders
  - Suppliers
  - Sub-tier suppliers

- SMEs (such as representatives from design, manufacturing, test, quality, procurement, and materials)

- Ensure that requirements are clearly documented and communicated between the prime contractor, their suppliers, and processors. This allows the suppliers the opportunity to address potential failure modes and better assess the risks and the level of testing needed.

- Ensure that suppliers clearly understand the user's application. This gives them the best opportunity to evaluate potential failure modes and to establish an appropriately perceptive screening test to detect the unwanted effect of the failure.

- See Section 7 for an example of a Change Notification Request form and instruction.

6.5 Customer Input—Key Characteristics (KCs)

Customer input is critical for a processor to identify if a process change could pose a risk. If the customer has provided guidance such as a PCN policy requiring prior notification, the processor is alerted to a need to involve the customer when considering a process change. Another way to obtain customer input is for the customer to identify KCs on a drawing. IAQG has published Aerospace Standard AS9103, *Variation Management of Key Characteristics* [13], which defines how and when to apply KCs to drawings or specifications.

6.5.1 What is a Key Characteristic

In general, any feature or process whose ***variation*** will have a significant effect on the performance of the characteristic for its intended use may be a key characteristic. This might include:

- dimensional features—thickness, diameter, length, etc.
- chemical concentrations
- time
- pressure, speed, rates, temperature, etc.

6.5.2 KC Identification

KCs are typically only called out on a drawing or specification where a customer has already recognized process variation criticality in the performance of a unit, a module, or a system. Once identified as a process that can influence a KC, the sub-tier supplier or in-house processor be required to flow down to other sub-tier suppliers that the process is identified as a KC and must be controlled.

6.5.3 KC Process Change Control

When a process is identified as one that can affect a KC, the following applies:

- The processor would initiate mitigation steps to reduce variation and thus, reduce the overall risk from process variation.

- The processor would be required to give prior notification to the customer of the intent to make a change to the process. The processor and customer would then engage in discussions on mitigation options to again reduce the risk from the process change.

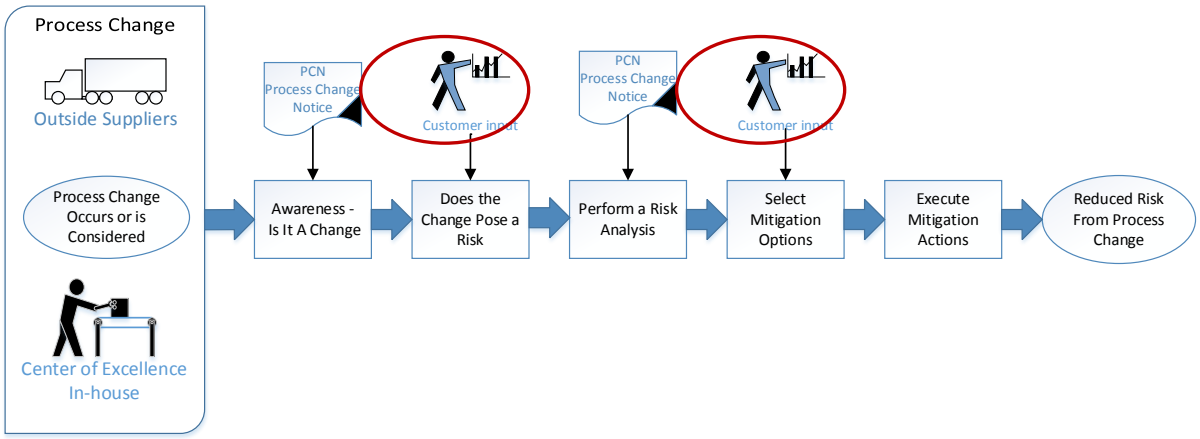


Figure 10. Common PCN—customer input points.

6.6 Process Failure Modes and Effects Analysis (PFMEA)

Performing a PFMEA proactively can mitigate many risks and should be used where appropriate. A PFMEA may be performed on the entire process of a supplier from receiving through shipping; however, this scope may require several days to complete and a broad array of SMEs in order to be thorough. By contrast, a PFMEA conducted on one process that is being considered for change may last only a few minutes to an hour and involve no more than a small number of SMEs. Because of this, completing a PFMEA on a potential process change is both feasible and economic.

The PFMEA provides a method of ranking and comparing the potential risks of process changes. The PFMEA then directs the team to consider mitigation options and select actionable items to execute. The PFMEA team may select a more perceptive screening test, a delta first article, or a delta process qualification. The goal of this team is to reduce the risk of the process change.

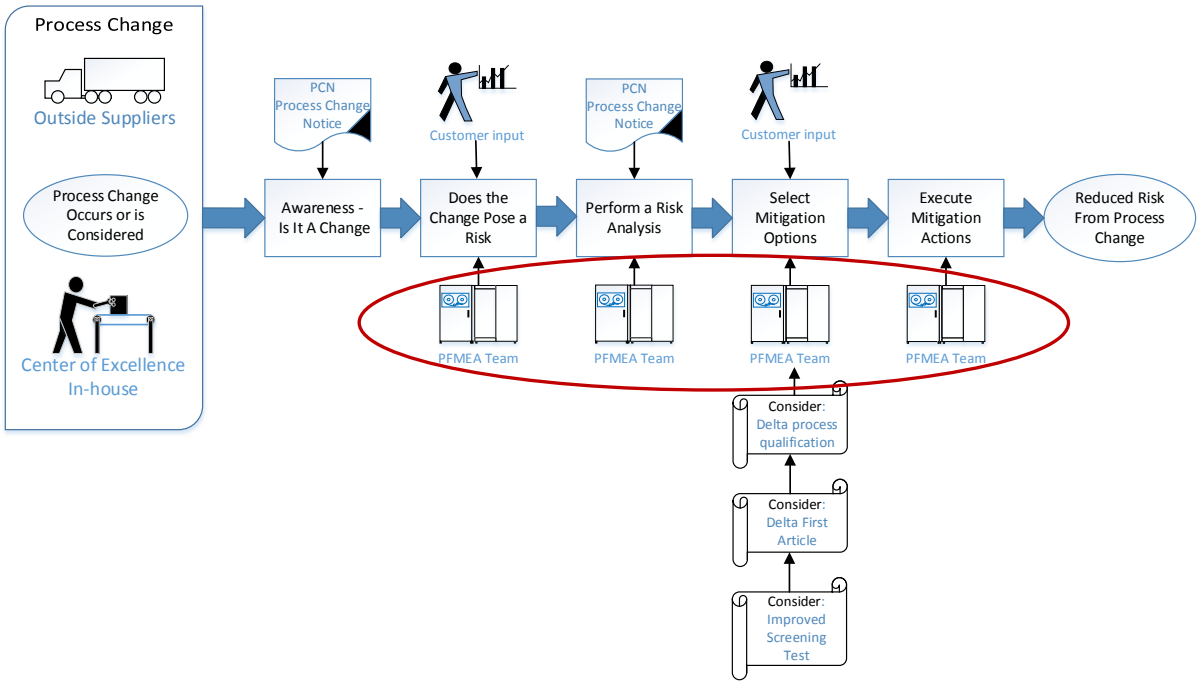


Figure 11. Common PCN—PFMEA team input points.

Establishing a perceptive test is key to reducing the risk and detecting the failure modes that have been introduced into a process. Testing is the most effective method to screen out potential escapes.

Raise the awareness among suppliers that changes have the potential to cause high-impact process escapes. There is no such thing as an "innocuous" process change. Every change should have an appropriate level of review which is defined in process change policy/procedure.

6.7 Recommendations

Based on these conclusions, there are several recommendations a program or a company (customer or supplier) should consider in order to reduce the risk of process change escapes making it into higher levels of manufactured hardware or impacting mission success:

1. Review and implement as required the AS9145 PFMEA process specifically to evaluate proposed process changes.

2. Consider implementing the process of identifying KCs per AS9103 on drawings or specifications where expected process variation can impact functionality.

3. Create or enhance current PCN policy/procedure to:

    a. Ensure there is a clear definition of what constitutes a process change

    b. Define the notification requirement for a proposed process change (prior to implementation of the process change being considered)

c. Include a summary review of completed, submitted, or pending PCNs at each product gate (such as critical design, manufacturing readiness, or test readiness) to help educate and spread awareness

d. Ensure flowdown through the supply chain (supplier to sub-tier suppliers) via contractual requirements, as is considered appropriate for key suppliers

e. Ensure proper disciplines (SMEs) are engaged in the risk assessments and mitigation plans of the proposed changes

4. Create a common industry (prime contractor level) PCN form (with the attributes of items listed above).

5. Ensure that all suppliers understand and comprehend the next level assemblies and also the environmental requirements of the final product. Whenever possible, encourage active participation and awareness, sufficient to be proactive to prevent adverse effects of lower-level process changes.

7. Additional Recommendations for Further Prime/Supplier Process Change Discussions

As noted earlier, a conscientious supplier or in-house processor may not be aware of any "process changes" that have occurred since qualification. However, when asked in a different way, a supplier may be willing to describe "improvements" that have been made to the process to make it easier, or to streamline or automate it. Bringing a supplier or processor to this understanding often requires someone with team facilitation skills.

7.1 Team Facilitation Techniques

Team facilitation is more of an art than a science, and requires significant experience in order to be effective and efficient. For a supplier, sub-tier supplier, or processor to feel comfortable enough to discuss process changes, a trained facilitator may be necessary. Some facilitation techniques that have proven to be effective are:

- Knowledge of group dynamics and how people tend to behave in a group setting
- Ability to "read" the team regarding confusion, progress, intimidation, etc.
- Ability to create a "safe environment" in which all team members are free to say anything they wish without fear of retribution or retaliation. The purpose is to find the truth, not place blame.
- Ability to deal with "intimidators" or those who are disruptive to the team process (including managers as appropriate)
- Ability to determine if the team is diverse enough and request additional members if required (specifically, hands-on process performers and/or customers)

A trained facilitator can pose questions that could expose process changes—questions that should be asked in non-threatening, safe, and inclusive environment. Some questions that can be asked of a supplier or processor to help expose process improvements (changes) include:

- **Methods**—Questions involving methods should include not only the methods that are value-added to the product, but also test and inspection methods as well as material handling and part marking, etc.
  - Have you been able to identify anything that could streamline or reduce duplication or waste in the process?
  - Are there multiple ways that you could build using this process?
  - Have you introduced any new "assembly aids" into the process?
  - Are there multiple shifts used to process the product?
  - Can the process be performed in different ways?
  - Have you improved your method for inspecting or testing the product?

- Have you improved the test program or any other automated software used to make the product?
- Has the manufacturing process been delayed for a long time and restarted?
- Can you create a plan to prepare for future methods/materials?

- **Machinery—**Questions involving machinery should not be limited to direct processing equipment but may include machinery for material handling, test, inspection, part marking, and packaging, etc.
  - Have you made any improvements in the equipment used in the process?
  - Are tools the best available?
  - Have you been able to find any equipment that reduces the labor used to make the part?
  - Can machinery be automated?
  - As your requirements change, have you been able to introduce any improved material handling devices?
  - Have you been able to improve your standard inspection equipment?
  - Have you introduced any improved or streamlined part marking or packaging equipment?
  - Have you had to use the backup tooling for any period of time?
  - Have you needed to refurbish any process equipment?
  - Is a preventative maintenance program in place for machinery?
- **Material—**Questions involving changes to materials shown on the bill of material (BOM) is expected to be reviewed through the ECP and is beyond the scope of this document. Material changes should focus on the incidental materials usually referred to as "expense" items or process consumables.
  - Have you been able to reduce costs of any of your expense items (adhesives, tapes, wires, lubricants, coolants, inks, etc.) since you qualified the process?
  - Have any of the expense items or consumables become obsolete or unusable, and have alternates been introduced?
  - Have options for different materials been introduced?
- **Environment—**Questions focusing on the environment might include changes to the location of equipment, storage within a factory or laboratory, or a change in the site. These questions may extend to similar changes at key sub-suppliers to the process.
  - Has the cleanliness or environmental conditions of the process been improved?
  - Has the process changed location or rearranged within the factory or laboratory?

- Has an additional manufacturing site been introduced?
- Is incoming material being inspected/stored in an improved environment?
- Is work in process (WIP) being stored in an improved environment?
- Is the finished product being stored in an improved environment?
- Has the method of shipment been improved?
- Have you changed the source for a subcontracted process (i.e., heat treating, plating) or a subcontracted inspection or test?

- **Personnel—**Skilled, trained personnel are often the key to well-run operations and processes, and disruption in the team can subtly impact quality of the final product.
  - Have any new personnel been hired?
  - Have there been significant changes in personnel due to downsizing?
  - Are there new contracts that have different areas competing for resources/people within the company?

The purpose of these questions is to help a supplier or processor identify changes that might affect the purchaser of the unit or the end user of the product. These questions are not exhaustive, but are meant to open for consideration the review of changes that go beyond typical form-fit-function changes. They can provide a basis for a conscientious supplier to recognize that a change to an existing process could represent a risk to a product in its end use even if the supplier was unaware of all of the conditions of the end use of a product.

The 27 questions could be flowed to processors (internal or external) when it is recognized that the performance of the module or unit is sensitive to the processes used in its manufacturing. The more that the processor knows about the end use (or downstream requirements) of the product, the more able they would be to identify and flag a process change that could increase product risk.

The questions are product-agnostic and as such, cannot be used to determine any risk. The questions are helpful to guide awareness that changes that may seem benign could pose an unacceptable risk.

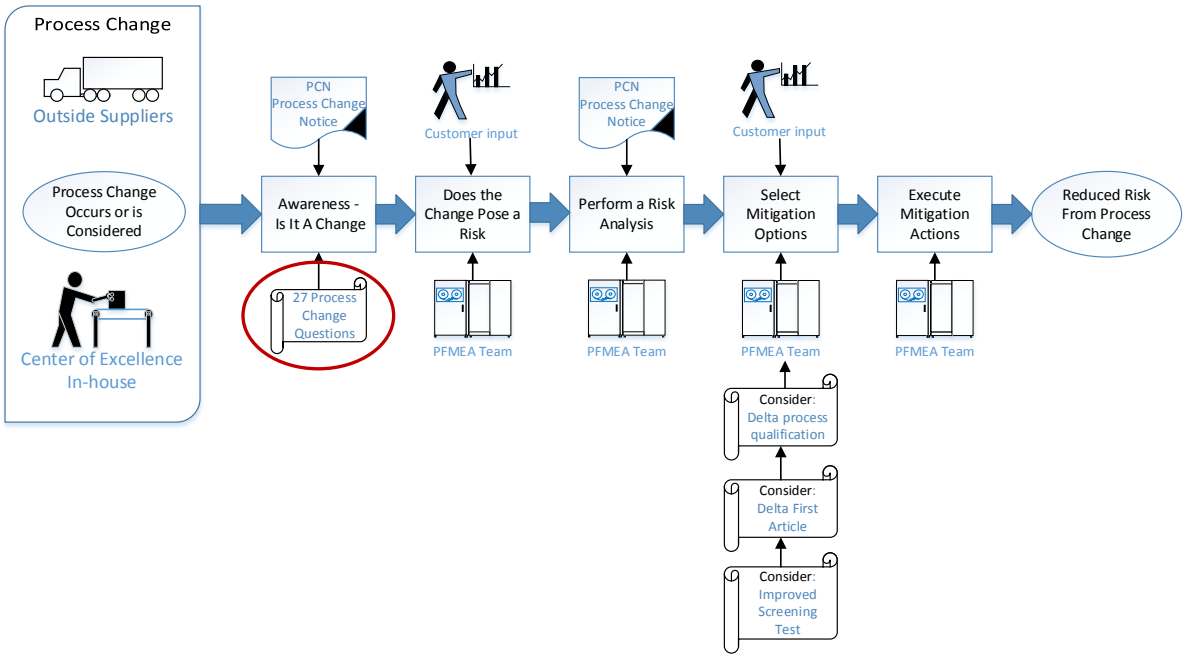


Figure 12. Common PCN—process change questions input point.

7.2 Sample PCN Form

A sample of a common PCN form is shown in Figure 13, with instructions for use shown in Figure 14.

Supplier Change Request/Notification for Approval

SCRN Section 1: Completed by the Supplier

1. SUPPLIER INFORMATION

Supplier Name:		Request Date:	
Manufacturing Address:		Phone Number:	
		Fax Number:	
Requestor:		e-Mail:	
Supplier Enterprise Supplier Directory (ESD) Number from PO:			

2. BUYER AND PURCHASE ORDER INFORMATION

Buyer Name:		Phone Number:	
Purchase Order (PO) Number(s) affected:			

3. PRODUCT INFORMATION

Part Number(s) on PO:		Revision(s):		Quantity:	
Effectivity Date(s):		Serial Number(s):		Date/Lot Code(s):	
Part Description:					

Inventory Status: *(Check all that apply)*

☐ Existing inventory ☐ Product currently being produced ☐ Products to be produced

Program(s) Impacted, if known:

4. REASON FOR CHANGE *(Check all that apply and include attachments as needed)*

☐ Plant Relocation	☐ Equipment Relocation	☐ New Equipment
☐ Process Change/Improvement	☐ Material Change	☐ Design Change
☐ Name/Cage Code Change	☐ Drawing Conflict	☐ Other *(Specify in Comments section)*
☐ Affordability/Producibility	☐ Change to Directed Sub-tier Supplier	

Comments:

Change Details:

5. RISK *(Check all that apply)*

☐ Technical	☐ Schedule	☐ Cost
☐ Quality	☐ Other	☐ None

List Potential risks and explain plans to mitigate Or attach Process FMEA if available:

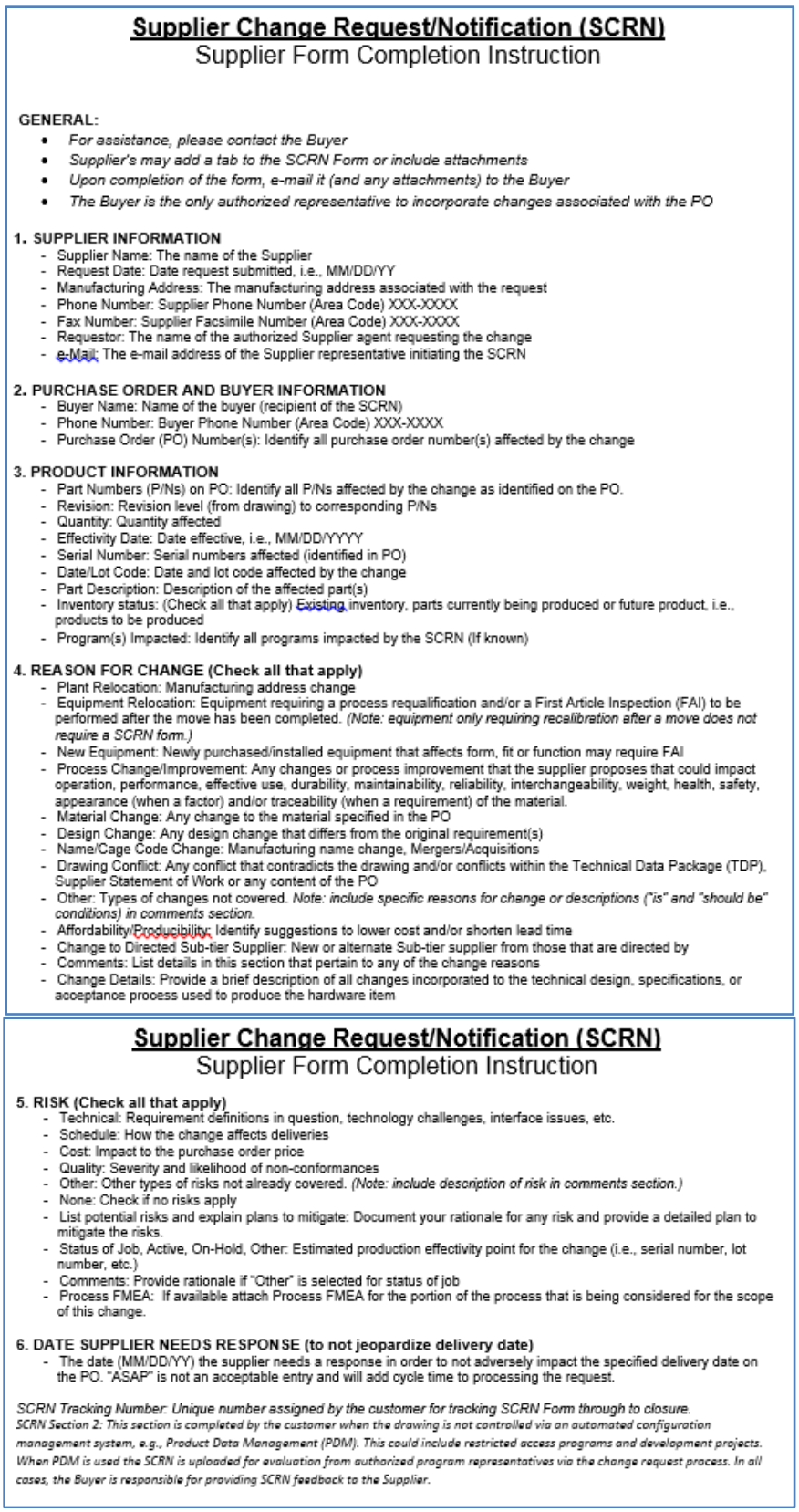
Status of job: ☐ Active ☐ On-Hold ☐ Other *(Specify in Comments section)*

Comments:

6. DATE SUPPLIER NEEDS RESPONSE *(Reasonable date (MM/DD/YY) to allow for processing)*

SCRN TRACKING No. *(For internal Customer use only when processing Section 2 of the SCRN Form)*

Figure 13. Sample PCN form.



Supplier Change Request/Notification (SCRN)
Supplier Form Completion Instruction

GENERAL:

- *For assistance, please contact the Buyer*
- *Supplier's may add a tab to the SCRN Form or include attachments*
- *Upon completion of the form, e-mail it (and any attachments) to the Buyer*
- *The Buyer is the only authorized representative to incorporate changes associated with the PO*

1. SUPPLIER INFORMATION

- Supplier Name: The name of the Supplier
- Request Date: Date request submitted, i.e., MM/DD/YY
- Manufacturing Address: The manufacturing address associated with the request
- Phone Number: Supplier Phone Number (Area Code) XXX-XXXX
- Fax Number: Supplier Facsimile Number (Area Code) XXX-XXXX
- Requestor: The name of the authorized Supplier agent requesting the change
- e-Mail: The e-mail address of the Supplier representative initiating the SCRN

2. PURCHASE ORDER AND BUYER INFORMATION

- Buyer Name: Name of the buyer (recipient of the SCRN)
- Phone Number: Buyer Phone Number (Area Code) XXX-XXXX
- Purchase Order (PO) Number(s): Identify all purchase order number(s) affected by the change

3. PRODUCT INFORMATION

- Part Numbers (P/Ns) on PO: Identify all P/Ns affected by the change as identified on the PO.
- Revision: Revision level (from drawing) to corresponding P/Ns
- Quantity: Quantity affected
- Effectivity Date: Date effective, i.e., MM/DD/YYYY
- Serial Number: Serial numbers affected (identified in PO)
- Date/Lot Code: Date and lot code affected by the change
- Part Description: Description of the affected part(s)
- Inventory status: (Check all that apply) Existing inventory, parts currently being produced or future product, i.e., products to be produced
- Program(s) Impacted: Identify all programs impacted by the SCRN (If known)

4. REASON FOR CHANGE (Check all that apply)

- Plant Relocation: Manufacturing address change
- Equipment Relocation: Equipment requiring a process requalification and/or a First Article Inspection (FAI) to be performed after the move has been completed. *(Note: equipment only requiring recalibration after a move does not require a SCRN form.)*
- New Equipment: Newly purchased/installed equipment that affects form, fit or function may require FAI
- Process Change/Improvement: Any changes or process improvement that the supplier proposes that could impact operation, performance, effective use, durability, maintainability, reliability, interchangeability, weight, health, safety, appearance (when a factor) and/or traceability (when a requirement) of the material.
- Material Change: Any change to the material specified in the PO
- Design Change: Any design change that differs from the original requirement(s)
- Name/Cage Code Change: Manufacturing name change, Mergers/Acquisitions
- Drawing Conflict: Any conflict that contradicts the drawing and/or conflicts within the Technical Data Package (TDP), Supplier Statement of Work or any content of the PO
- Other: Types of changes not covered. *Note: include specific reasons for change or descriptions ("is" and "should be" conditions) in comments section.*
- Affordability/Producibility: Identify suggestions to lower cost and/or shorten lead time
- Change to Directed Sub-tier Supplier: New or alternate Sub-tier supplier from those that are directed by
- Comments: List details in this section that pertain to any of the change reasons
- Change Details: Provide a brief description of all changes incorporated to the technical design, specifications, or acceptance process used to produce the hardware item

Supplier Change Request/Notification (SCRN)
Supplier Form Completion Instruction

5. RISK (Check all that apply)

- Technical: Requirement definitions in question, technology challenges, interface issues, etc.
- Schedule: How the change affects deliveries
- Cost: Impact to the purchase order price
- Quality: Severity and likelihood of non-conformances
- Other: Other types of risks not already covered. *(Note: include description of risk in comments section.)*
- None: Check if no risks apply
- List potential risks and explain plans to mitigate: Document your rationale for any risk and provide a detailed plan to mitigate the risks.
- Status of Job, Active, On-Hold, Other: Estimated production effectivity point for the change (i.e., serial number, lot number, etc.)
- Comments: Provide rationale if "Other" is selected for status of job
- Process FMEA: If available attach Process FMEA for the portion of the process that is being considered for the scope of this change.

6. DATE SUPPLIER NEEDS RESPONSE (to not jeopardize delivery date)

- The date (MM/DD/YY) the supplier needs a response in order to not adversely impact the specified delivery date on the PO. "ASAP" is not an acceptable entry and will add cycle time to processing the request.

SCRN Tracking Number: Unique number assigned by the customer for tracking SCRN Form through to closure.
SCRN Section 2: This section is completed by the customer when the drawing is not controlled via an automated configuration management system, e.g., Product Data Management (PDM). This could include restricted access programs and development projects. When PDM is used the SCRN is uploaded for evaluation from authorized program representatives via the change request process. In all cases, the Buyer is responsible for providing SCRN feedback to the Supplier.

Figure 14. Instructions for sample PCN form.

7.3 PCN Implementation Considerations and Caveats

Beyond the circumstance where a conscientious supplier or an internal processor may be simply unaware of process changes, there are other factors which can make an effective risk inquiry difficult or not feasible. One consideration is that a supplier may have multiple customers for a product from a given process. For example, a supplier may produce a set of harnesses through a specific automated process. These harnesses may be sold to multiple customers for multiple applications. A change to the automated manufacturing process could involve discussing the change and understanding the end-use environments for each application from each customer. Each customer might have unique risk factors and unique likelihoods of detecting unwanted consequences. The scope of the inquiry may seem so daunting (for technical, cost, and/or time aspects) that a supplier may simply choose not to engage any customer. The process change is introduced without the insight that the customer might provide and the supplier simply "hopes for the best."

Another example—one that was seen frequently in the analysis of the problem set that the team investigated—was that if a product made it through the next screening test after a process change was introduced, then the change was considered innocuous. Little or no regard was given to the perceptivity of the screening test to screen out pre-identified failure modes from the change.

In this circumstance there is no opportunity to prevent an unwanted consequence. There is only the investigation that is part of a standard root cause investigation and the risk analysis that can be employed after the escape. A skilled facilitator using a thorough process change mitigation technique can still have benefit to contain and recover from the unwanted effect, but any opportunity to prevent the effect has passed. For these cases, flowing to key suppliers within a controlled document the appropriate language of what a process change is and why it is important that the customer be included ahead of the proposed change may be the best prevention.

A conscientious customer should communicate to key suppliers:

- What constitutes a process change
- Why it is vital to notify or include the customer in a review of the change before it is implemented
- Which process change mitigation techniques should be used to assess the global risk of a proposed process change

The customer or prime wanting to introduce the language of controlling process changes to their supply base clearly faces their own unique considerations. There are cost and resource impacts to the customer for introducing and promoting process change mitigation techniques. Before a prime or a tier 1 supplier institutes a plan to manage process changes at the supply base, certain infrastructures need to be institutionalized. If a prime would like to require process change reviews and assessments before a process change is implemented at a supplier, a team of SMEs by commodity or process needs to be assembled and trained on the specific techniques for investigating a potential change. There might even be facilitator training prerequisites. The team would need to be able to quickly understand the proposed change identification and predict potential unwanted outcomes. They should be able to assess the severity and the likelihood of occurrence of each unwanted outcome. They must be able to identify where the issue would be detected and what mitigation steps might be feasible. This would constitute the agenda for a meeting with process SMEs and the supplier or processor. If many suppliers started to submit multiple requests for process change reviews, the customer's resources could easily be overwhelmed. With limited resources, a customer may want to only introduce process mitigation at key suppliers of modules or units

with high-risk characteristics. Finally, it is important to emphasize that individuals trained and qualified in RCCA facilitation, methods, tools, and processes need to be present in or available to the higher-tier suppliers.

8. References

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Appendix A. Trade Association & Process Control Group Summaries

A.1 American Institute of Aeronautics and Astronautics (AIAA)

ANSI/AIAA S-102.2.4-2015

Capability-Based Product Failure Mode, Effects and Criticality Analysis

(FMECA) Requirements

August 2015

The FMECA Requirements Standard establishes the structured process for conducting a product design review.

A.1.1 Background

This is a systems engineering approach for a comprehensive review of a product designed to provide improved safety and reliability and is best used before the design is solidified or before a product is manufactured. This can be of some help in establishing what elements of a design are the most critical and can in turn point to suppliers and/or processes that have the potential to cause significant mission risk if a process change were to be introduced.

In Section 3.2.1.4, Risk Management, the standard states: "the supplier should have a risk management system capable of performing root cause analysis, process maturity analysis, and corrective action implementation. Examples of risk include ... process changes and facility moves."

A.1.2 Evaluation

This standard provides a strong methodology for establishing the elements of a product design which can in turn direct a customer to the key suppliers that are to be considered for process control flowdown language. The purpose of this document is primarily to assess product design risks. This standard does not—nor is it intended to—provide detailed direction to assess process changes.

Reviews of this standard and other standards published by AIAA have not produced any substantive discussion of process change-induced failure modes. There is no discussion of what may constitute a process change. None of the standards discuss process change-related risk analysis including severity, likelihood of occurrence, or the need for early detection of the potential escapes.

A.2 IPC – Association Connecting Electronics Industries (IPC)

IPC-HDBK-001

February 2012

The IPC Handbook-001 is a guide to the use of J-Standard-001 (J-STD). The handbook is of particular value because it explains the J-STD changes by paragraph.

A.2.1 Background

The IPC Handbook (and the J-STD-001) provide define samples of process changes:

Major Process Changes

- Fabrication houses
- Laminates (FR-4 to CEM-1)
- Metallization (HASL tin-lead to palladium flash)
- Solder masks (dry film to an LPI)
- Fluxes, type and/or formulation (RMA to water soluble)
- Cleaning, method and/or chemistry (Freon TMS to aqueous saponifier)

Minor Process Changes

- Bake or cure cycles
- Minor process variations in fabrication
- Change from a 6-percent solids flux to a 2-percent flux of the same formulation
- Equipment or tooling where the output satisfies the requirements of the Standard (lead bending dies or wire strippers)

In Appendix B of the handbook, there is a discussion on how to validate the acceptability of a major change in a proven process prior to its implementation. The handbook outlines the testing protocol needed to document the validation. It further states that "…process changes can involve a change in one of the process steps…" and may "…pertain to a change in bare board supplier, solder resist or metallization…."

The standard stipulates that "…whenever major elements of proven processes are changed…." there should be a re-evaluation of the requirement of the J-STD. Further, the handbook states that there is a need for formal communication with the sub-suppliers: "…proper communication between the manufacturers and their subcontractors or suppliers is critical."

A.2.2 Evaluation

While this handbook shows some deference to the customer's application, there is less emphasis on any detrimental potential impact of a process change on the user or customer in the handbook. The handbook does state that failing to conform to the standard "…can reasonably be expected to have an adverse impact on the useful (design) life, functional capability, [severity] or reliability (failure rate in service) of

the product…[likelihood of occurrence].” There is no discussion of the likelihood of detection of a potential failure resulting from a process change nor is there any discussion of any specific methodology of assessing or ranking the risks of a potential process change to the end user.

Further, the handbook states that the user does have the authority to specify additional risk factors and to flow these down to the manufacturer, but this guidance falls short of directing the manufacturer to elicit direct input from the end user prior to enacting a process change, or to provide a prompt notification if a change has occurred.

A.3 U.S. Food and Drug Administration (FDA)

Guidance for Industry: Q10 Pharmaceutical Quality System

April 2009

The Q10 document provides end-to-end recommendations and best practices based on ISO concepts to the pharmaceutical manufacturing industry to support good medical practices (GMPs).

A.3.1 Background

From the introduction to the Q10 document:

> "This internationally harmonized guidance is intended to assist pharmaceutical manufacturers by describing a model for an effective quality management system for the pharmaceutical industry, referred to as the pharmaceutical quality system."

The main sections cover an overall pharmaceutical quality management system, including a corrective action and preventative action (CAPA) system and a change management system (Section 3).

A.3.2 Evaluation

Additional lower-level documentation identified a medical device quality systems (MDQS) manual with more detail regarding how to establish a manufacturing change system that is consistent with Q10 and GMP (Chapter 9).

The change system that is described is very similar to Aerospace industry manufacturing practices (Class I and Class II type changes, engineering change orders, engineering change requests [ECRs], etc.)

None of the documents examined so far go into much detail on the change processes or the specific makeup of the review teams (i.e., what disciplines are needed to properly review, etc.). The references in these documents/manuals point to ANSI/ISO/ASQ Quality Management Systems (Q9000-2000, A9001-2000, Q9004-2000) for details.

A.4 International Aerospace Quality Group (IAQG)

Aerospace Standard (AS) 9145

Final draft was scheduled to be released in July 2016

AS9145, *Requirements for Advanced Product Quality Planning and Production Part Approval Process*, is a guide to the aerospace community that provides, among other elements, a standard methodology for a risk analysis of a manufacturing process and developing mitigation plans approved by the using customer. The standard in turn directs the reader to SAE J1739, *Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)*, for specifics on the application of this methodology.

A.4.1 Background

As of the writing of this report, AS9145 is in final draft form and was scheduled to be released in July 2016.

Researching both this standard and the references within the Society of Automotive Engineers (SAE) standard provides examples of process changes:

Typical process functions could be, but are not limited to:

Load => Grind => Unload => Inspect => Induction Harden => Repair => Wash

AS9145 states "…this standard is invoked…when previously approved…processes undergo change (e.g., introduction of a new production process, change to existing production process, change of production source, addition to the existing production sources.)"

The methodology of using a PFMEA is most valuable before a process change is implemented. The SAE J1739 standard states that "Up front time spent…completing an FMEA, when…process changes can be most easily and inexpensively implemented, will minimize late change crises. An FMEA can reduce or eliminate the chance of implementing a preventive/corrective change that would create an even larger concern."

Severity evaluation criteria are shown in Appendix A of J1739. The standard underscores the need to involve the customer "…an interfacing system team or customer should be consulted in order to comprehend the propagation of effects." The standard further defines "The customer includes all users of the product. Customers are end users (external), manufacturing and assembly operations (internal) and service operations (external). Internal customers can be interim users of the product such as the next higher-level assembly or users of the process such as subsequent manufacturing operations."

Appendix B of the standard discusses the likelihood of occurrence and outlines the evaluation criteria.

Appendix C discusses the likelihood of detection and gives evaluation criteria for this analysis.

A.4.2 Evaluation

The PFMEA methodology shown in the AS9145 standard is thorough with a strong customer focus. When applying this methodology to a single identified process change in advance of the implementation, the scope is limited to a finite list of potential failure modes. Thus, the application of the PFMEA methodology can be cost-effective. The PFMEA appropriately places the onus for getting the customer involved on the manufacturer before the prospective process change is implemented.

A.5 Joint Electron Devices Engineering Council (JEDEC)

JESD46C

August 2001

JEDEC Standard No. 46C establishes procedures to notify customers of semiconductor product and process changes.

A.5.1 Background

This document establishes a communication procedure that shall exist between a customer and a supplier for the changes in semiconductor products and processes.

JEDEC Standard No. 46C does not define specific process changes, but it says changes shall be classified as either major or minor.

A major change is "a change that may affect the form, fit, or function of the product or adversely affect the quality or reliability of the product," while a minor change is "a change that does not affect the form, fit, function, quality, or reliability of the product."

A.5.2 Evaluation

This document states a supplier needs to have a documented PCN which shall classify the changes as either major or minor. The PCN should contain a minimum number of elements, which should include:

- documentation of the supplier's PCN requirements
- definition of changes
- timing
- documentation that will be delivered to the customer
- record retention requirements

The document outlines how customers must be notified of major changes, while notifications of minor changes may or may not occur depending on customer requirements. The notification needs to include all affected customers. The supplier is left to determine how to notify the customer. The customer shall "be notified a minimum of 90 days before the proposed first ship date of the product." The supplier should consider publishing a general PCN "on a website to allow for potentially missed customers to view current and past PCNs."

Once the supplier has submitted a PCN, the customer has set time of 30 days to respond. If the customer does not respond, their lack of response will be considered an acceptance. An acceptable response or any concerns need to be submitted by the customer within 90 days. If the customer requires additional time, this will need to be negotiated between the supplier and customer.

There is no documented response time to the customer's concerns, though it does state that a customer has 30 days to follow up on the supplier's response.

A.6 Nadcap

(Formerly NADCAP, the National Aerospace and Defense Contractors Accreditation Program)

p-r-i.org/nadcap/eAuditNet

April 2015

The eAuditNet is a web-based system, developed and maintained by the Performance Review Institute (PRI) to support and improve efficiency in the Nadcap auditing and accreditation system.

A.6.1 Background

The web-based system (eAuditNet) provides operating procedures including OP 1107 (Post Accreditation Actions) which states to notify PRI of the following changes:

- Ownership
- Company name
- Location
- Address (without location change)
- Cessation of operations
- Inability to meet requirements (e.g. fire, flood, etc.)

The Quality Management System Requirements Audit Checklist (AC7004 RevE, *Quality Management System Requirements for Nadcap Accreditation*, Purchasing Information, Section 7.3.2) states the requirements regarding the need for the supplier to:

- Notify the organization of nonconforming product
- Obtain organization approval for nonconforming product disposition
- Notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location, and, where required, obtain organization approval
- Flow down to the supply chain the applicable requirements, including customer requirements

Several sections of the checklist mention the organization shall establish methods to ensure that monitoring and measurements of processes are controlled. Several sections reference process change and guidance on controls to ensure changes are controlled and communicated. The sections that include this information are:

- General (4.2.1)
- Purchasing (7.3.1)
- Purchasing Information (7.3.2)
- Control of Production Process Changes (7.4.2)

- Control of Monitoring and Measuring Equipment (7.4.8)
- Monitoring and Measurement of Processes (8.2)
- Control of Nonconforming Product (8.4)

A.6.2 Evaluation

Within the eAuditNet portal of Nadcap, there are two documents that reference process change. Those documents are OP 1107, *Post Accreditation Actions*, and AC7004 Rev E of the Quality Management System Requirements Audit Checklist. The first document (OP 1107), only states when PRI is to be notified and "Process Change" is not listed. The second document (AC7004) has several sections that reference "Process Change" and provides guidance on controls and communication strategies.

A.7 Society for the Advancement of Material and Process Engineering (SAMPE)

A.7.1 Background

The Society for the Advancement of Material and Process Engineering (SAMPE) is a global professional member society that provides information on new materials and processing technology via conferences, exhibitions, technical forums, publications, and books in which professionals in this field can exchange ideas.

SAMPE was suggested to the topic team as a trade organization which may have manufacturing change processes or standards to draw from.

A.7.2 Evaluation

After a review of SAMPE journals and symposium proceedings and discussions with two individuals at The Aerospace Corporation with SAMPE organization experience, it was concluded that there were no process change standards that could be drawn from this society.

"SAMPE mainly sponsors materials conferences and exhibits and publishes proceedings. They are not a standards organization." A March/April 2015 article from *SAMPE Journal* refers to composites standards and procedures developed outside SAMPE by American Society of the International Association for Testing and Materials (ASTM, formerly American Society for Testing and Materials) and Composite Materials Handbook (CMH-17). Both groups, however, do have SAMPE member representation.

Charts were sent to the team from a manufacturing problem prevention program (MP3) sponsored by the United States Air Force (USAF) Space and Missile Systems Center (SMC), circa late-1980s. The MP3 was intended to disseminate problem prevention strategies (as short one-pagers) horizontally across systems program offices (SPOs) and contractors supporting Air Force programs; a descendant of the MP3 (lessons learned) is currently managed out of the Corporate Chief Engineer's Office (CCEO) at Aerospace. SAMPE co-sponsored at least one MP3 symposium in October 2008. Those 2008 proceedings discussed a variety of new manufacturing technologies and processes, but were not focused on the topic team's interest, "innocuous process changes."

A search and review of SAMPE in Google Search found another tangential connection to the topic team in *Bridging the Centuries with SAMPE's Materials and Processes* from the 45th International SAMPE Symposium and Exhibition in Long Beach, California [14]. Starting on page 420 of this document, an article titled "Seven Element Qualification Process" briefly touches on materials requalification after process changes, but mentions that adhering to a systematic technical review after a change does not replace "those listed in MIL-HDBK-17 or standardized test processes such as those published by ASTM or SACMA".

A.7.3 Conclusion

There appear to be no manufacturing change process standards proposed or published by SAMPE; however, the review leads to other potential sources at ASTM, CMH-17 (supersedes MIL-HDBK-17), and Society of Advanced Composite Materials Association (SACMA).

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Process Change Assessment Techniques

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