

Risk-Informed Quality Assurance

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Thought of the Day

The whole problem with the world is that fools and fanatics are always so certain of themselves, but wiser people so full of doubts

Bertrand Russell



The Two Modes of Mishap Prevention





Avoiding Complacency

1. Know the enemy within:

Know your internal quality system weaknesses, and be continually working to remedy them.

2. Know the enemy without:

Know your external quality risks, and be continually working to mitigate them.

3. Focus on risk:

Plan and execute around risk. Don't waste time/resources assuring minimal-risk attributes.

4. Connect the dots:

Think system...know mission and context...

AS9100: 2009



A New (and needed) Focus on Risk

7.1.2 Risk Management

The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

- a) assignment of responsibilities for risk management,
- b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
- *c) identification, assessment and communication of risks throughout product realization,*
- d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria,
- e) acceptance of risks remaining after implementation of mitigating actions.

critical items ... key characteristics ... special requirements



The Risk Iceberg



Risk Management for Exploration

- Known Knowns: (Systems Engineering, Quality Processes and Program Management)
 - Disciplined program and mission management processes and people
- Known Unknowns: (Continuous Risk Management)
 - Reduce uncertainties with analysis, ground and flight test
 - Prioritize and manage residual risk (including uncertainty) with training, conservative procedures and quality plans
- Unknown Knowns: (Continuous Process Improvement)
 - Communications , Communications, Communications
 - Improve data analysis tools and techniques (e.g. trending)
- Unknown Unknowns: (Continuous Research, Test and Eval)
 - Exercise Engineering Curiosity
 - Continuously challenge assumptions, models and analyses
 - Be ready for adverse effects (emergency systems)





High Residual Risk* Acceptance at NASA

- Tech Authority (relevant tech requirement owner) approves based on technical merit, and
- Safety Tech Authority approves based on risk acceptability, and
- Risk Taker (and supervisory chain of command) volunteers to take the risk, and
- Only then does Program or Ops Manager get to "accept the risk"

*Residual risk is that extra level of risk over and above what is inherent in the design requirements



NASA Quality Policy NPD 8730.5



... mitigate risks associated with noncompliance. Risk considers the likelihood of noncompliance and the consequences associated with noncompliance, including the maturity, complexity, criticality, and value of work performed ...





... periodically reevaluated and **5**5 adjusted based on changes to risk factors.





C ... attain confidence levels that are commensurate with the severity of consequences that would be incurred in the event of noncompliance.



Remember Past Lessons

No one wants to learn by mistakes, but we cannot learn enough from successes to go beyond the state of the art.

Henry Petroski

To Engineer is Human

Become a Student of Past Quality System Failures









Vacuum Chamber thought to have been a pressure vessel



Control rod lodged in ceiling of SL-1 reactor building.



USS THRESHER



First in her class

She was fast, quiet, and deep diving. The leading edge of US Submarine Technology



Apollo 1 Command Module



First in her class

She was larger & far more complex than any previous design. The leading edge of US Spacecraft Technology

NASA

- Inadequate Workmanship -

THRESHER

Improperly brazed pipe joint



Poorly brazed pipes led to the electrical shortage that led to the loss of the USS THRESHER.

Apollo 1

"The board found numerous examples in the wiring of poor installation and poor workmanship".



Figure 2: Wires where the fire was suspected to have started.



- Inadequate Fabrication Processes -

THRESHER

Brazed piping joints exposed to full submergence pressure

Apollo 1

Teflon wire coating could be easily damaged or penetrated by abrasion

- Ineffective Quality Program -

THRESHER

Apollo 1

Portsmouth Naval Shipyard inspectors using newly developed ultrasonic testing techniques identified numerous instances of faulty brazed joints. Many brazed joints on the THRESHER were never UT'd. Kennedy Space Center inspectors cited multiple instances of deficient parts, equipment, and workmanship.



- Vulnerable Design -

- Inadequate Emergency Recovery -

- Unforeseen Failure Mode -

THRESHER

- Reactor shutdown
- Impaired access to vital equipment
- Compromised ballast tank blow



Wreckage from the USS THRESHER's sonar dome can be seen on the ocean floor.

Apollo 1

- Single gas atmosphere
- Flammable materials
- Inward opening hatch







The Enemy Within

- Know your Quality System Weaknesses -

	Documentation - AS9100	Management Responsition	Resource Management AS9100 paragement	Planning/Customer	Design - AS9100 Para 7.1, 1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,	Supply Chain - AS9100 -	Production/ Process . AS9100 Para 7 -	Calibration/Metrology_ AS9100 Para	General Quality Assurance AS9100 Para o	Monitoring/Audit - AS9100 Para 8.2	Control of NCM - AS0100	Analysis of Data - Asoci	Corrective and Prevents.	QA SCORE Para 8.5
BP Oil Refinery Blast	Х	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	13
Lewis Spins Out of Control		Х	Х	Х	Х	Х	Х			Х		Х	Х	11
USS Thresher				Х	X	Х	Х		Х	Х				7
Supercritical - SL-1 Reactor	X	Х	Х		X		Х	Х			Х	Х	Х	10
US Forrestal in flames	X	Х	Х	Х	Х	Х	Х							8
	3	4	5	4	7	3	8	2	2	3	2	3	3	

Proximate Causes
Underlying Causes
Score
0 = not a contributing cause

1 = underlying cause

2 = Proximate/primary cause

The marked boxes indicate ineffective QMS elements and a failure of quality assurance auditing to identify & correct these shortcomings.





The Enemy Without

- Counterfeit Parts -

New versus Refurbished leads



Backtop peeling away. Sand marks evident



Dual Markings



NASA

National Semiconductor does not use ": " in part numbers



Missing Serial Number



Acetone Swipe





Workers extract plastics from discarded electronics in Guiyu, a few hours' drive northeast of Hong Kong. The city has 5,500 family workshops handling e-waste. © 2006 The Seattle Times Company



Laborer de-soldering circuit boards over a coalfired grill. Rock in the box is where boards are hit to remove solder. Pliers are used to pluck off chips which go into various buckets. The boards are then tossed into a pile for open burning. © BAN



Total Counterfeit Incidents:



U.S. Department of Commerce March, 2009

The Enemy Without (cont) - Metal Whiskers -







Tin Whisker on Electromagnetic Relay Shorting Terminal to Case



Zinc Whiskers on <u>Hot Dip Galvanized</u> Steel Pipe



Using Risk to Prioritize

Separate the vital few from the trivial many

Joseph Juran

606F System Design Top LS Mission Risk Drivers









Risk Informed, or Risk Averse?

To your own discretion therefore must be left the degree of danger you risk, and the point at which you should decline, only saying we wish you to err on the side of your safety, and to bring back your party safender on if it be Letter to Meriwether Lewis: 1803 with less information.



GITTERDUNN...

