
Conformity Assessment as a Risk Management Tool

Prepared for

*International Symposium
on
Advanced Radio Technologies
(ISART)*

July 25-26, 2012

Boulder, CO

New Sharing Schemes

Requirements for success:

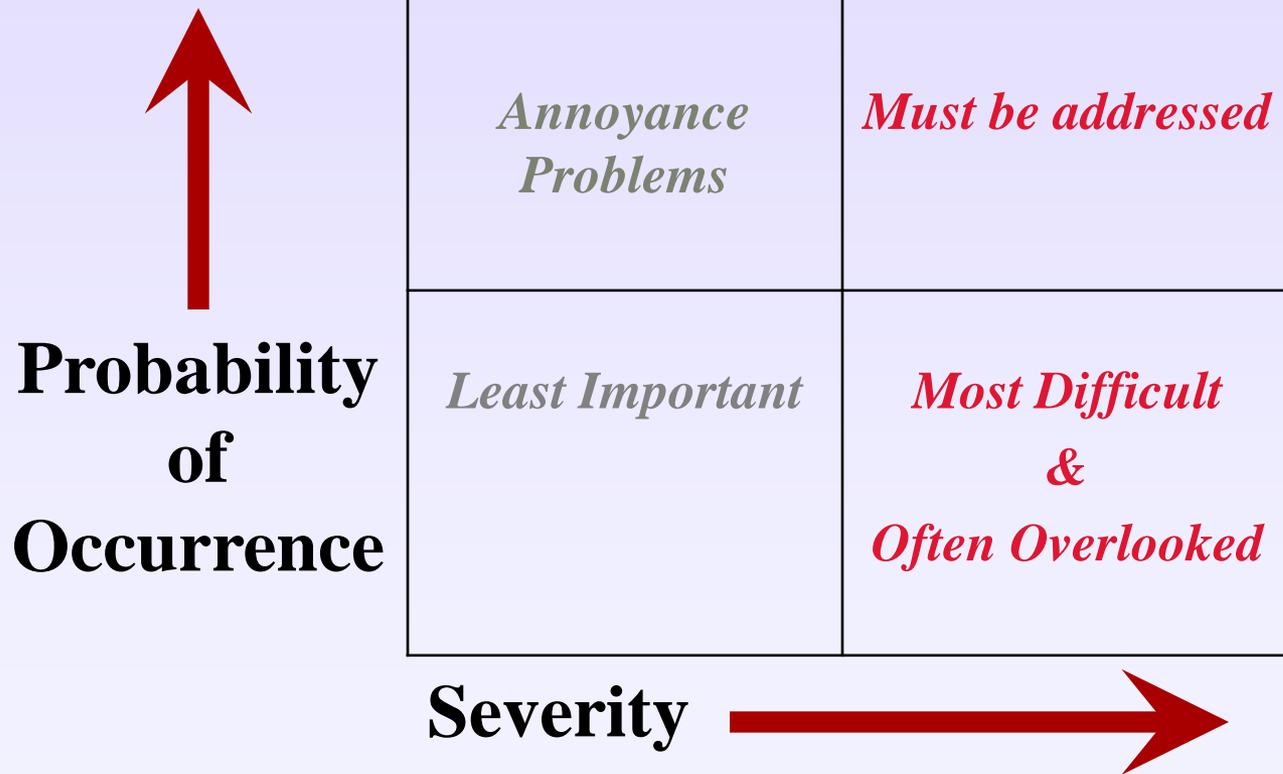
- 1. Provide a compelling value.**
- 2. Risks must be known and be manageable.**

Regulators use conformity assessment systems, primarily product certification, to manage risks that impact public interest and insure that they remain below acceptable levels.

Public Interest Concerns:

- **Wireless systems coexist.**
- **Non-interference with technological infrastructure**
 - **Hearing Aids**
 - **Medical Devices**
 - **Control Systems**
 - **Personal Electronics**
- **Supports ongoing innovation**
- **Allows unforeseen adaptations**

Categories of Risk



**Certification programs have a
common path they follow.**

Stage 1 – A check-box activity

• Are instructions provided in the documentation for securing the system?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
• Usable for curbside voting?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
• How to setup or modify audio files	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
• How to adjust volume	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

**Stage 2
Experience Based**

**↑
Probability
of
Occurrence**

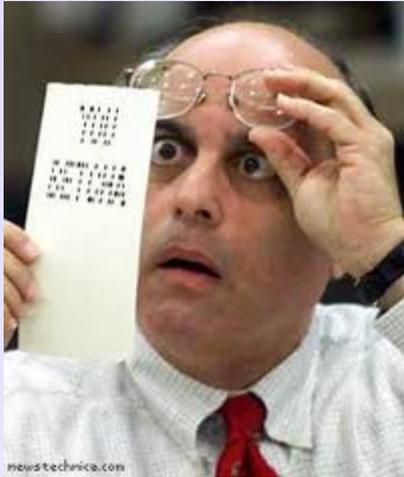


**Stage 3
Design Based**

**→
Severity**

TEM Consulting, LP





Bush v Gore
was a
low probability, high impact event

So was the Fukushima meltdown

‘Black Swan’ events are often created by well known risks that combine in a rare event to create a dramatic impact.

Approaches Risk Management

- **Nuclear and Aviation Industry**
ISO 61508 – Functional Safety
- **FDA & Medical Devices**
ISO 14971 – Risk Management for Medical Devices

IEC 61508 Target Safety Values

IEC 61508's SILs for "on demand" safety functions...

Safety Integrity Level (SIL)	Average probability of a dangerous failure of the safety function, "on demand" or "in a year"	Equivalent mean time to dangerous failure, in years*	Equivalent confidence factor required for each demand on the safety function
4	$\geq 10^{-5}$ to $< 10^{-4}$	$> 10^4$ to $\leq 10^5$	99.99 to 99.999%
3	$\geq 10^{-4}$ to $< 10^{-3}$	$> 10^3$ to $\leq 10^4$	99.9 to 99.99%
2	$\geq 10^{-3}$ to $< 10^{-2}$	$> 10^2$ to $\leq 10^3$	99% to 99.9%
1	$\geq 10^{-2}$ to $< 10^{-1}$	> 10 to $\leq 10^2$	90 to 99%

* Approximating 1 year = 10,000 hrs of operation

"Failure" includes any error, malfunction or fault that causes a hazard

Product certification alone is unlikely to manage the risks to acceptable levels.

What is needed are complimentary process such as field monitoring and real time risk mitigation.

Questions?

Contact Information

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