

## Afterwords – Where Do We Go From Here?

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### Where do we go from here?



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### Halifax 7, Ottawa, 2007

Ottawa – strange word meaning:  
“Land of the Regulators”

*What is the proper role of regulation in patient safety?*

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**What is the proper role of regulation in patient safety?**

Could it help? Could it hurt? If so, how?  
The regulatory cascade  
Premature fixation, or, can floors become ceilings?

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**Can it help?**

No hazardous industry has improved safety in the absence of external regulation  
Race to the bottom  
What if safety costs more?  
Safety management systems  
Mandated by regulation  
Interestingly, include the regulator as part of the regulated system

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**The 'Safety Case'**

1982 – Seveso Directive on Major Accident Hazards  
1984 – UK HSE Control of Industrial Major Hazards  
Require (among other things):  
A written report – the Safety Case  
A continuing argument – updates for each major change, after accidents or critical incidents

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**The 'Safety Case'**

1982 – Seveso Directive on Major Accident Hazards

1984 – UK HSE Control

**Where is the Safety Case for the new Trondheim hospital?  
Or, for adding a new service (eg, Level 1 Trauma Center) to existing operations? Or a new computer system?**

A call update after an incident



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**Can it hurt?**

**O**N a muggy May afternoon in 1996 an emergency dispatcher in southern Florida got a call from a man on a cellular phone. The caller said, "Yes. I am fishing at Everglades Holiday Park, and a large jet aircraft has just crashed out here. Large. Like airliner-size."

ValuJet 592

Caught fire after takeoff and crashed in the Everglades while attempting to return to the airport

2 pilots, 3 flight attendants, 105 passengers died

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**Can it hurt?**

NTSB investigation found:

- Fire in forward cargo hold
- Started in 5 boxes of oxygen generators
- No caps on firing pins
- Generators had never been used

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**Can it hurt?**

NTSB investigation found  
Fire in forward cargo hold  
Started in 5 boxes of oxygen  
No caps on firing pins  
Generators had never

**Being transported  
safety regulations  
be replaced after  
service**

seventy-two logged 910 hours over several weeks for replacing oxygen generators, in most cases because they had "expired" -- reached the end of their approved lives. According to ValuJet work card No. 0069, which was supplied to investigators, the second step of the seven-step removal process was *If generator has not been expended, install shipping cap on firing pin.* This required a gang of hard-pressed mechanics to draw a verbal distinction between canisters that were "expired," meaning most of the ones they were removing, and canisters that were *not* "expended," meaning many of the same ones, loaded and ready to fire, on which they were expected to put nonexistent caps. Also involved were canisters that were expired and expended, and others that were not expired but were expended, and course, there was the set of new replacement canisters, which were both unexpended and unexpired. If this seems confusing, do not waste your time trying to figure it out -- the SabreTech mechanics

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**In summary, important contributors to accident were:**

Engineered safety devices *required by regulation*  
Removed from service as *required by regulation*  
Mishandled because *regulations were confusing*

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**The regulator's unhappy lot (Reason)**

1. Public perceives them as ineffective, in bed with the industry
2. Industry insiders perceive them as arrogant and out of touch

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**JCAHO inspection team**



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**The regulatory cascade**

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| 1. Regulatory guidance pronounced at a very high level | 1. "Ensure good communication at shift change" |
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**The regulatory cascade**

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| 1. Regulatory guidance pronounced at a very high level           | 1. "Ensure good communication at shift change" |
| 2. Translated into more specific terms by field operatives (CYA) | 2. "Shows use of effective handoff procedures" |

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**The regulatory cascade**

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| 1. Regulatory guidance pronounced at a very high level           | 1. "Ensure good communication at shift change"     |
| 2. Translated into more specific terms by field operatives (CYA) | 2. "Shows use of effective handoff procedures"     |
| 3. Translated again by organizational representatives (CYA)      | 3. "Everyone must sign the handoff sheet, or else" |

*The very high levels express surprise and protest that's not at all what they meant*

*Regulations appear misguided, ineffective, "busy work" in the work context and lose legitimacy*

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**Other problems**

Premature fixation  
West African rituals for the corn god

Brought corn to the people near the beginning of the world

Which must have been around 1500




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**Other problems**

Premature fixation  
West African rituals for the corn god

Could floors become ceilings?

*Might changing room configuration become a violation?*

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**The healthcare standoff**

Reasonable, desirable changes for improvement are proposed

But the specifics are technically difficult

*Emphasize the difficulties and use that to stop change* vs *Pound the table and insist on poorly thought out compliance*

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