The “Safety Case” Regulatory Regime: Its Potentials and Challenges

Personal Observations

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Background of the “Safety Case”

Piper Alpha Offshore Platform Accident, July 6, 1988 - killed 167

“The Piper Alpha accident in 1998 caused more fatalities than any incident in the history of offshore oil and gas operations and was considered the costliest man-made disaster at that time” (NRC/TRB, 2016, p. 90)
Lord Cullen’s Finding

“Many current safety regulations are unduly restrictive because they impose solutions rather than objectives. They also are out of date in relation to technological advances. Guidance notes lend themselves to interpretations that discourage alternatives. There is a danger that compliance takes precedence over wider safety considerations and that sound innovations are discouraged. “
Cullen’s report expresses the view that management systems should describe

- Potential major hazards on an installation and identify appropriate safety measures,
- the safety objectives,
- the system by which those objectives are to be achieved,
- the performance standards to be met, and
- the means by which adherence to those standards is to be monitored.  (NRC/TRB 2016, p. 91)
BP Deepwater Horizon Accident
April 20, 2010
BP Deepwater Horizon
BP Deepwater Horizon Accident
April 20, 2010

11 workers lost their lives and 16 others were seriously injured.

The flow continued for nearly 3 months before the well could be completely killed, during which time, nearly 5 million barrels of oil spilled into the gulf.
Site Visit – Deepwater Nautilus in the Gulf of Mexico
Deepwater Nautilus
From BP’s Bly Report, P. 91, Sep 2010

Figure 7. Deepwater Horizon Driller’s Cabin circa 2001.
BOP
BOP
BOP
BOP
What is the “Safety Case”

• It is a proactive approach
• It is a structured argument, supported by a body of evidence that provides a compelling, comprehensible and valid case that a system is acceptably safe for a given application in a given context
What is the Safety Case?

• ... a risk-based argument and corresponding evidence to demonstrate that all risks associated with a particular system have been identified, that appropriate risk controls have been put in place, and that there are appropriate processes in place to monitor the effectiveness of the risk controls and the safety performance of the system on an ongoing basis.

• ... to provide a structured argument, supported by a body of evidence that provides a compelling, comprehensible and valid case that a system is acceptably safe for a given application in a given context.

(Exploring the potential use of safety cases in health care, April 2014)
What is the Safety Case (cont.)

Safety Case consists of few critical components:

• identifying all risks associated with a particular system,

• putting in place appropriate risk controls,

• and processes in monitoring the safety performance of the system on an ongoing basis.
The Primary Function of Safety Case

- Is to prove that a system is critically safe and that the risks associated with it is reduced to “As Low As Reasonably Practicable (ALARP)”.

Ultimate Safety Responsibility

- Safety Cases legislations adopted by countries such as United Kingdom and Norway from as early as 1974, emphasize on the importance of transitioning the ultimate responsibility of achieving and maintaining safety from the regulator to the industry itself.
Today in Offshore Industry

Today, offshore regulatory regimes in Norway, Australia, the United Kingdom, New Zealand, and the Netherlands focus on operator safety management systems as opposed to prescriptive regulations. (NRC/TRB, 2016, P. 90)
Safety Case in the UK
Safety Case in the UK Healthcare Industry

Evidence:
Using safety cases in industry and healthcare

A pragmatic review of the use of safety cases in safety-critical industries – lessons and prerequisites for their application in healthcare

December 2012

Exploring the potential use of safety cases in health care

Report of the Health Foundation’s Safety Cases Working Group
Safety Case in the EU

2015 No. 398

HEALTH AND SAFETY

ENVIRONMENTAL PROTECTION

The Offshore Installations (Offshore Safety Directive) (Safety Case etc.) Regulations 2015

Made - - - - ***
Laid before Parliament ***
Coming into force - - 19th July 2015
Singapore’s Approach to Safety Case
Singapore’s Characterization of a Safety Case

What is a Safety Case?

A Case which an MHI makes to the regulators, setting out how risks from major accidents hazards can be reduced to ALARP*, ensuring safe operations in a sustainable manner.

A Safety Case includes details of:
- Hazard identification process
- Identification of hazards with the potential to cause major accidents
- Evaluation of major accident risks
- System/procedures put in place to control them
- Measures to limit major accident consequences

MHIs to convince the regulators that the strategy for managing safety is satisfactory, through the adoption of ALARP principle

* ALARP: As Low As Reasonably Practicable
Common Problems with Safety Cases

1. Intelligible
2. Valid
3. Complete
4. Evidential
5. Robust

(UK ONR, July 2016, p. 18)
Common Problems with Safety Cases

1- Intelligible

• Much of the safety case is written in the form of a technical dissertation with insufficient attention paid to the needs of the users, hence the document does not provide a sufficiently clear view of the safety case to facilitate safe operation. (UK ONR, July 2016, p. 18)
Common Problems with Safety Cases (cont.)

2- Valid

• The safety case doesn’t take proper account of incidents that have occurred in the facility or elsewhere. Incidents are usually considered as part of longer term periodic review processes but there should be more direct links between Operating Experience (OPEX) systems and impact on the extant safety case. (UK ONR, July 2016, p. 18)
Common Problems with Safety Cases (cont.)

3- Complete

• The safety case strategy and scope is inadequate. This can be due to time pressure and/or lack of consideration of viable options before deciding on the course of action. The resultant safety case may be technically correct but it is not the appropriate case for the circumstances.

• ALARP arguments are presented retrospectively after decisions have been made and the ALARP justification is ‘tagged on’ at the end of a safety case. If there is inadequate consideration of options at the safety case strategy stage, or an inappropriate option is selected, the outcome is unlikely to satisfy ALARP requirements. (UK ONR, July 2016, p. 19)
Common Problems with Safety Cases (cont.)

4- Evidential

The safety case makes claims on the robustness of the plant and the ability of the operator to take appropriate and timely action, but with little or no substantiation for human factors aspects (including the effects of abnormal conditions) (UK ONR, July 2016, p. 19)
Common Problems with Safety Cases (cont.)

5- Robust

The safety case doesn’t distinguish between the design basis (what the facility has been designed to do and the major assumptions made in its design) and the design base analysis (analysis of accidents for which designer makes explicit safety provisions) (UK ONR, July 2016, p. 19)
Safety Case and Safety Culture

“The adoption of Safety Cases needs to be accompanied by appropriate guidance and training as well as a continuing development of safety culture maturity.”

Conclusion
Managing the Risks of Organizational Accidents
JAMES REASON

Organizational Accidents Revisited
JAMES REASON

1997

2016
Professor James Reason

“Societies, just like the operators of hazardous systems, put production before protection. As we have seen, safety legislation is enacted in the aftermath of disasters, not before them. There is little or no political kudos to be gained from bringing about a non-event, although, in the long run, meeting this challenge successfully is likely to be much more rewarding. Every society gets the disasters it deserves. Let’s hope that, in the next millennium, the regulators are seen to deserve something better than has so far been the case. Then, perhaps, we will all be safer.” (1997, p.188)