

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 They also are out of date in relation to technological advances.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 installations 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

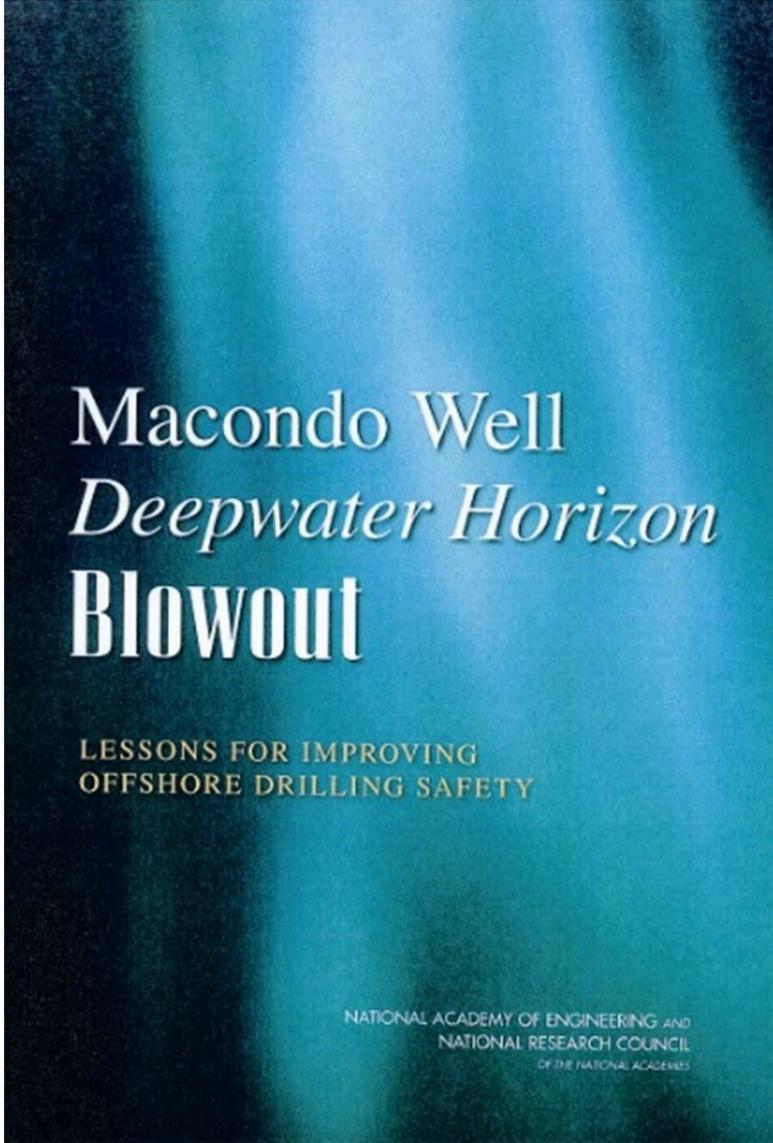


BP Deepwater Horizon Accident

April 20, 2010

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

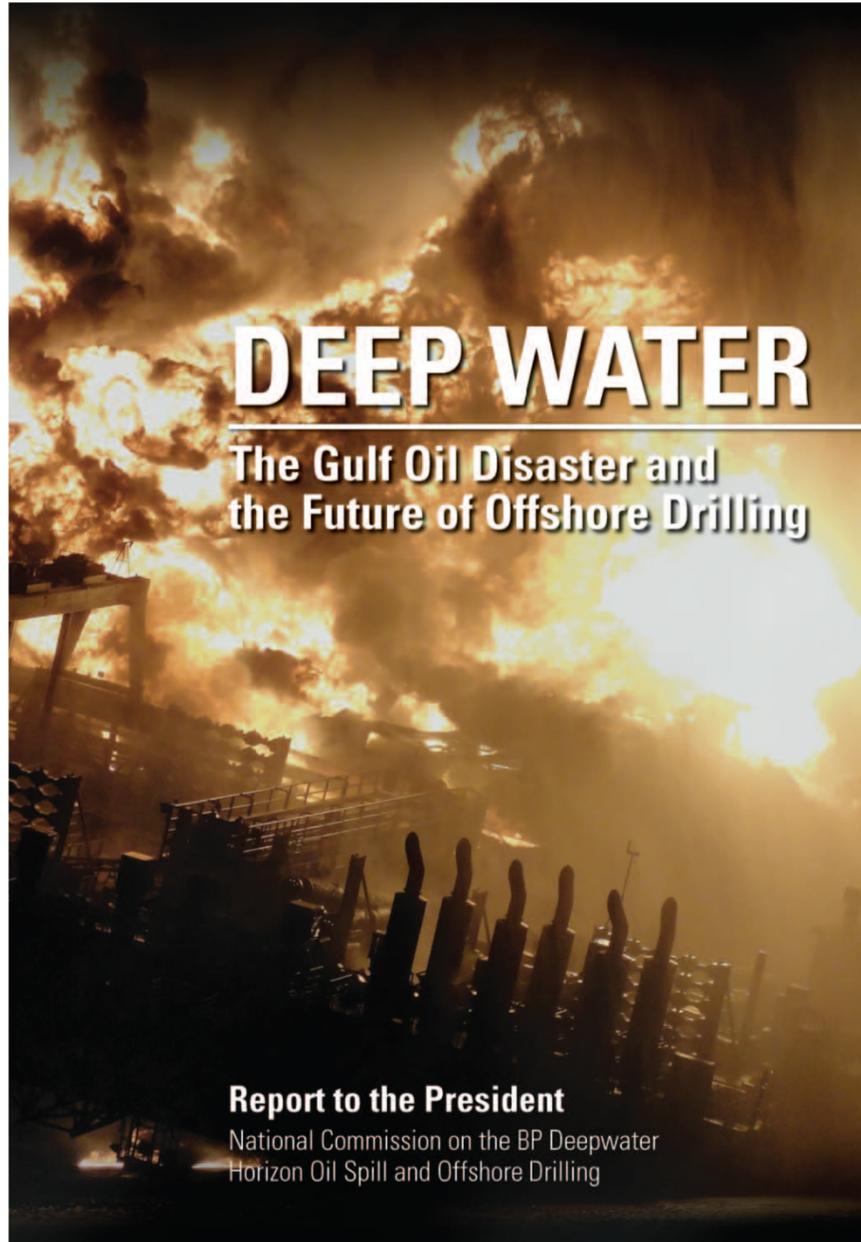
The flow continued for nearly 3 months before the well could be completely killed, during which time, nearly **5 million barrels** of oil spilled into the gulf.



Macondo Well
Deepwater Horizon
Blowout

LESSONS FOR IMPROVING
OFFSHORE DRILLING SAFETY

NATIONAL ACADEMY OF ENGINEERING AND
NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES



www.oilspillcommission.gov

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)”.

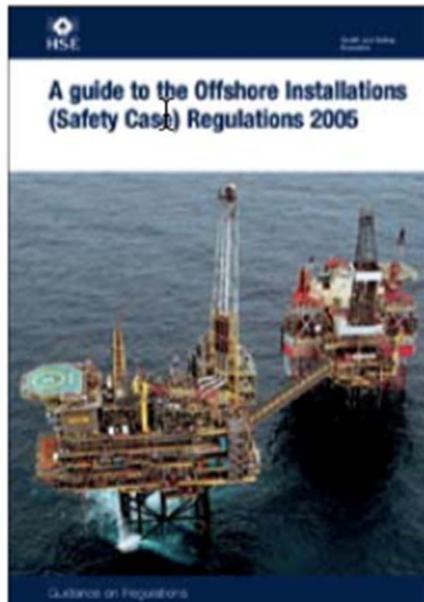
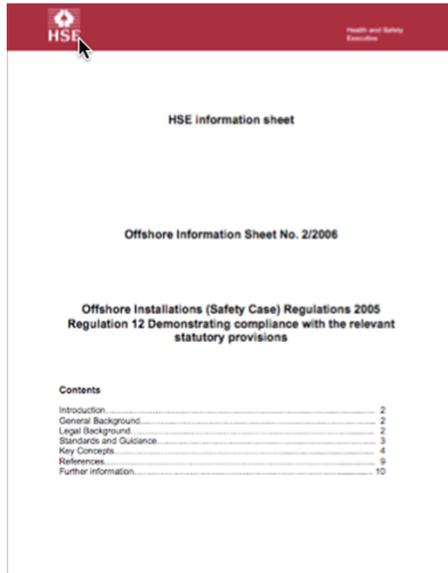
Ultimate Safety Responsibility

- 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



ONR GUIDE			
THE PURPOSE, SCOPE, AND CONTENT OF SAFETY CASES			
Document Type:	Nuclear Safety Technical Assessment Guide		
Unique Document ID and Revision No:	NS-TAST-GD-051 Revision 4		
Date Issued:	July 2016	Review Date:	July 2019
Approved by:	Graham Heys	Professional Lead	
Record Reference:	Trim Folder 1.18.1211. (2016/230683)		
Revision commentary:	This is a "minor refresh" and has been updated to be fully compatible with ONR Safety Assessment Principles 2014. It incorporates minor additional explanations. A more extensive update is in preparation, but will need some stakeholder engagement prior to issue. In the meantime the current version is fit for purpose.		

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

STATUTORY INSTRUMENTS

2015 No. 398

HEALTH AND SAFETY

ENVIRONMENTAL PROTECTION

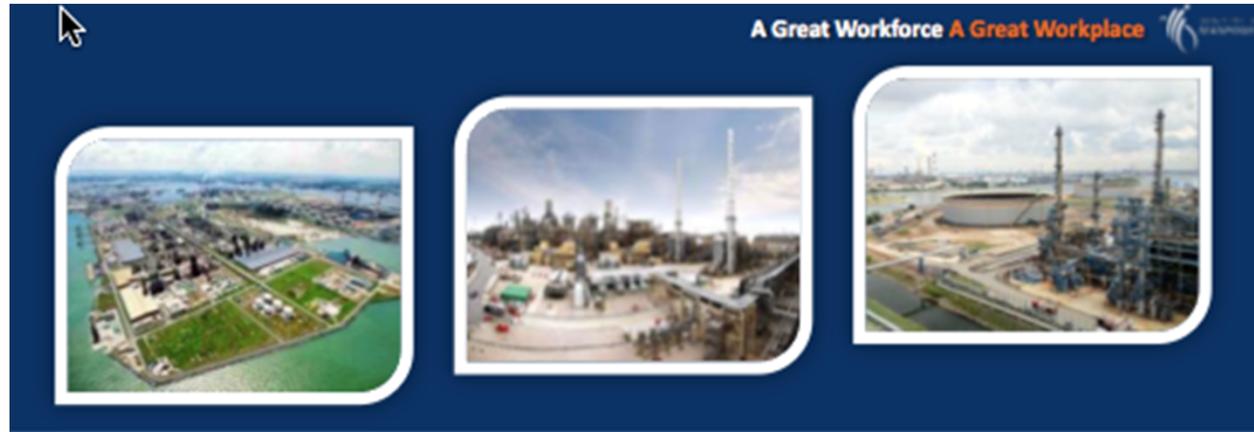
The Offshore Installations (Offshore Safety Directive) (Safety Case etc.) Regulations 2015

Made - - - - *******

Laid before Parliament *******

Coming into force - - *19th July 2015*

Singapore's Approach to Safety Case



The Safety Case Journey for Singapore

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OSH Specialist Department
Ministry of Manpower

WSHI ICES MOM
27 Nov 2015

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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

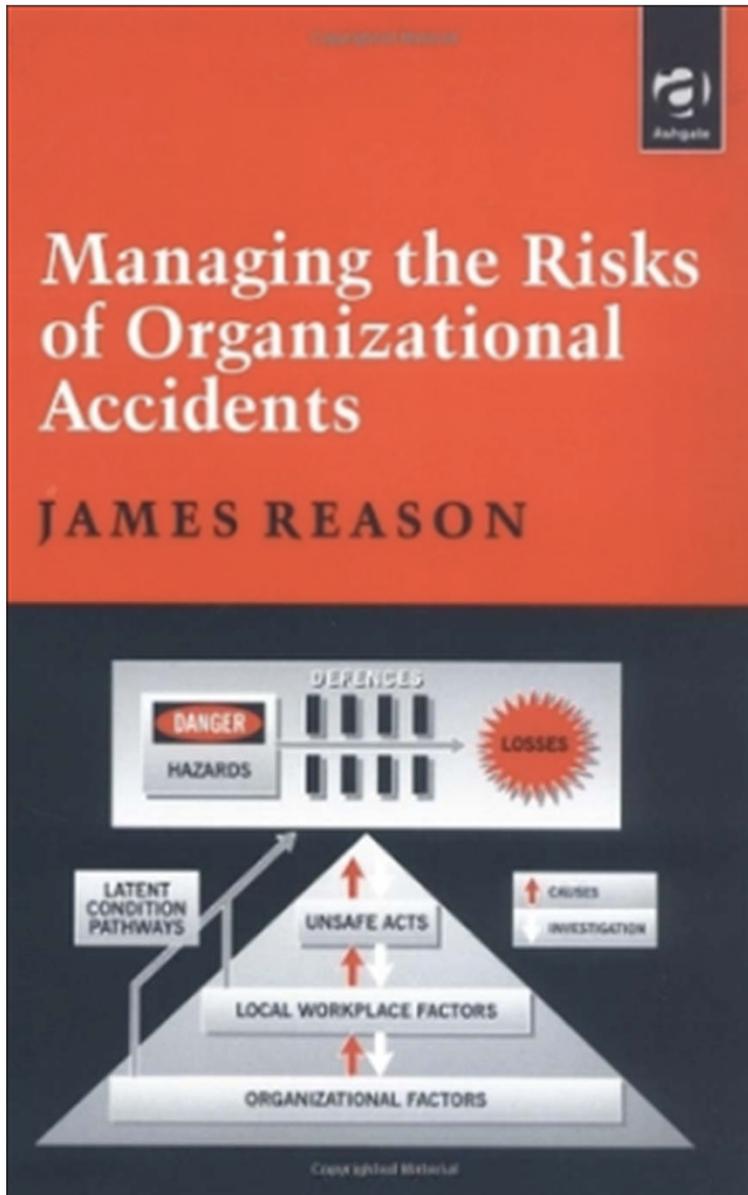
The safety case doesn't distinguish between the design basis (what the facility has been designed to do and the major assumptions made in its design) and the design base analysis (analysis of accidents for which designer makes explicit safety provisions) (UK ONR, July 2016, p. 19)

Safety Case and Safety Culture

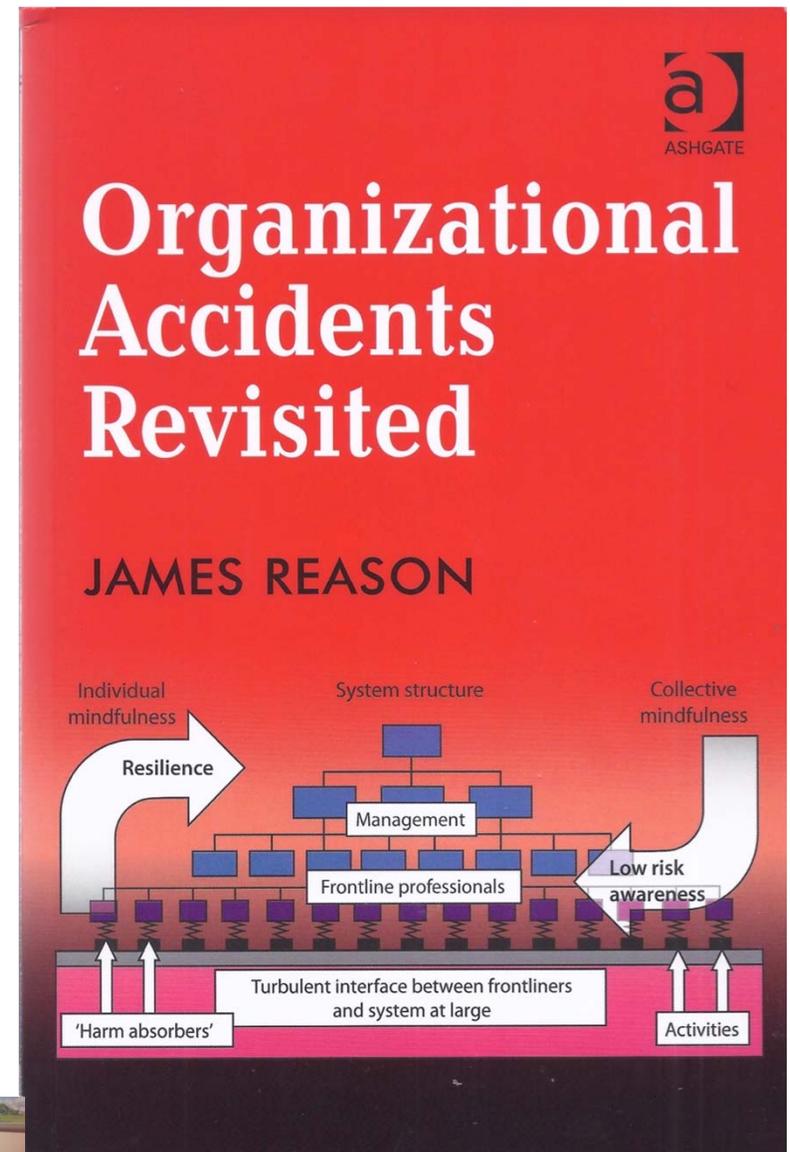
“The adoption of Safety Cases needs to be accompanied by appropriate guidance and training as well as a continuing development of **safety culture maturity.**”

A conclusion of the: *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).

Conclusion



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)