PARALLEL SESSIONS ON

OTHER HIGH RELIABILITY ORGANIZATIONS' APPROACHES TO SAFETY

Papers submitted

PAPERS SUBMITTED TO PARALLEL SESSIONS ON OTHER HIGH RELIABILITY ORGANIZATIONS' APPROACHES TO SAFETY

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MANAGING THE ORGANISATIONAL AND CULTURAL PRECURSORS TO MAJOR EVENTS – RECOGNISING AND ADDRESSING COMPLEXITY

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Abstract

Research at the Safety Systems Research Centre has drawn out the organisational and cultural precursors leading to major events in several industries. It has shown that these are strikingly similar regardless of the industry in which they occurred. Organisational and cultural issues contributing to twelve high-profile events were analysed from the published reports and grouped under eight generic headings. Sets of 'Expectations' were then developed from the findings as statements of good practice, which if recognised and implemented, should enable organisations to build stronger defences against the occurrence of future events. These expectations and associated 'probing' question sets are being refined by working with industry. The paper also presents examples of the use of Hierarchical Process Modelling and Causal Loop Modelling to explore the complexity of the findings and develop vulnerability tools. Examples are given relating to organisational learning and contractor management.

1. INTRODUCTION

Research at the Safety Systems Research Centre (SSRC) at Bristol University has shown that very similar organisational and cultural precursors can be identified when a wide range of major events across several industry sectors are analysed - whether they occur during day-to-day operations, outages or during specific projects. The events studied, using the findings from authoritative investigations, all involved failures in the complex interaction between people, processes and 'plant' in which 'hard' engineered systems were embedded in 'soft' systems.

The current University of Bristol study, was broadly based on the development of understanding of the causes of organisational accidents developed by researchers such as Reason [1], Turner, Blockley and Pidgeon (e.g.[2,3]) and,

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more recently, by Leveson [4] and Hopkins [5]. Some of the ideas in these papers have been applied in practice by those such as Goh et al [6,7] and Underwood et al [8]. The approach in the current paper draws on an earlier study using a similar approach carried out in BNFL and reported by Taylor and Rycraft [9] to an earlier IAEA conference and some of the results presented here have recently been published in the Journal 'Process Safety and Environmental Protection' [10].

The initial intention of the work was to promote awareness of the findings and their similarities and to raise awareness among a wide range of stakeholders from leaders and policy makers in industry to engineers and others at the 'sharp end'. Ensuring that regulators are also aware of the identified issues is also seen as vital. The intention has been to try to promote learning and debate about the issues rather than to attribute blame or highlight particular events. Because the study draws out the similarities in the deeper lying, less apparent organisational causes of events across industries, a further objective is that different sectors will be enabled to work together to develop approaches to minimise the frequency of occurrence of events and the SSRC is currently facilitating this approach.

The next step in the research has been to help organisations (and their regulators) to gain a better understanding of their vulnerability to such accidents. This is being achieved firstly, by developing from the findings organisational 'objectives' or 'expectations' which will help enable gaps in current organisational requirements to be recognised. This is a valuable first step, but work is also being carried out to generate from these 'objectives', more penetrating 'questions' to enable organisations to recognise the extent to which expectations are being met in practice. The strength of the link between aspiration and 'reality' - the need for intentions to be embedded in the bloodstream of the organisation - is considered to be vital.

Two other areas of research are being pursued and these are considered important if the identified issues are to be systematically addressed within a 'systems thinking' framework. First, a structured process (akin to the use of event trees and PRA in more conventional engineering analysis) is being developed to assist organisations and regulatory bodies systematically to assess vulnerability in any or all of the key issues discussed later in the paper (condition monitoring). An example of the approach is shown below in relation to 'organisational learning'. Second, it is apparent that addressing vulnerabilities, once these have been recognised, requires new processes and insights. This is because the recognised issues are complex, often interactive (changing one can often lead to unpredicted consequences in others), and there are different timescales involved in recognising, promoting and embedding changes. It is, we believe, necessary to develop techniques which can be used as 'flight simulators' in the management of change and to ensure that the best holistic indicators are being measured to try to ensure that unpredicted outcomes are minimised. The technique of System Dynamics (SD) provides a very promising approach. Two examples, one relevant to organisational learning and the interaction between leaders and those at 'the sharp end', and one dealing with the important issue of managing the supply chain (use of contractors) are presented.

2. THE EVENTS STUDIED

Twelve major events (including four nuclear events occurring since 2000) have been studied in detail and the findings from formal investigations drawn out and categorised. These were chosen as being relatively recent, representing a cross section of events in relevant industries and because they were of particular interest to industry and regulatory partners in the research. Also, importantly, the investigations chosen for analysis, considered deeper issues in some depth rather than stopping at more simplistic conclusions - such as 'there was insufficient competence' or 'procedures were not followed'. It is planned that this 'directory' of event findings will be expanded. The full list upon which the research is currently based is:

(a) Port of Ramsgate walkway collapse - UK, September 1994 [11];
(b) Heathrow Express NATM tunnel collapse during construction - UK, October 1994 [12];
(c) Longford gas plant explosion - Australia, September 1998 [5,13,14];
(d) Tokai-mura criticality accident - Japan, September 1999 [15,16];
(e) Hatfield railway accident - UK, October 2000 [17];
(f) Davis Besse pressure vessel corrosion event - USA, February 2002 [18];
(g) Loss of the Columbia Shuttle - USA, February 2003 [19];
(h) Paks nuclear plant fuel cleaning event - Hungary, April 2003 [20];
(i) Texas City oil refinery explosion - USA, March 2005 [21–23];
(j) Loss of containment at the THORP Sellafield reprocessing incident - UK, April 2005 [24];
(k) Buncefield fuel storage explosion - UK, December 2005 [25];
(l) Loss of the Nimrod XV230 aircraft - Afghanistan, September 2006 [26].

3. FINDINGS

Organisational and cultural findings contributing to each event were assembled under several generic headings in order to provide a basis for considering vulnerabilities in a systematic way, recognising the overlaps and interactions between them are fully recognised. The headings used in the current research were:

(a) Leadership issues;
(b) 'Local' operational attitudes and behaviours (operational ‘culture’);
(c) The impact of the business environment (often commercial and budgetary pressures);
(d) Oversight and scrutiny;
(e) Competence and training (at all levels);
(f) Risk assessment and risk management (also at all levels);
(g) Organisational learning;

(h) Communication issues.

Other issues of importance, such as management of the supply chain (relevant to several of the events) and the learning for regulators, both within their organisations, and in their response to some of the events listed, have also been drawn out.

We now summarise some of the frequently occurring findings for several of the above areas which are of particular relevance to the conference. These are not comprehensive (because of paper length considerations), but 'give a flavour' of the common types of precursor that were recognised across many of the events. In what follows we use the term 'process safety', since it is commonly used to distinguish the safety in carrying out a complex 'process' from more 'everyday' industrial or personnel safety - exemplified by minimising slips, trips and falls. In the context of this paper, 'process safety' can be interpreted to mean nuclear safety.

3.1. Leadership

Ineffective leadership is considered by the authors to be the most fundamental issue leading to most of the events analysed. Specific issues identified as important factors in the events include the following:

— The need for commitment to 'process safety' from ‘the top’ and the communication of this as a core value to the workforce in a compelling and intelligible way, such that the priority attached to this in the organisation is beyond question;
— A requirement for a strong understanding of operational ‘reality’ obtained from high leadership visibility and a questioning attitude about matters as they really are, rather than encouraging the transmission upwards primarily of ‘good news’;
— The development of clear organisational structures and accountabilities, which minimise complexity. This ensures clarity about roles and responsibilities. It also facilitates good communication and minimises the existence of ‘silos’ which can reduce team working and learning;
— The need to ensure that the organisation maintains its capability as the ‘controlling mind’ and is an intelligent customer for services that it buys in, with an understanding of the responsibility and role of duty holder or licensee;
— Ensuring that there is an effective safety management system (SMS), that this is encourages and is supported by a strong safety culture, and that ‘policy’ is translated into operational requirements and procedures in such a way that the users of the SMS understand the basis of requirements and receive help and advice, where necessary, in implementation. In particular

there is a need for a clear and well-understood 'balance' between requirements from the 'centre' and discretion given to operational units;

- The need for sufficient information effectively to monitor and review performance – for example, reviewing on a regular basis a suitably detailed range of performance indicators for process safety which contain leading as well as lagging parameters taken together with event/near-miss reports and 'audit' and 'scrutiny' findings. This is further discussed in relation to 'oversight, below;
- The existence of processes which recognise the importance of process safety issues and integrate these with decision making about other aspects of business performance. Issues relating to process safety must always be given sufficient prominence (e.g. when compared to the review of financial and commercial performance) such that an acceptable balance between process safety and commercial performance can be retained and that the importance of the link between them is understood in the decision making process. This requires that senior managers and leaders have sufficient understanding of the risks to make informed judgements;
- The existence of an approach to communication which transmits key expectations and issues to the workforce and which encourages and facilitates constructive feedback which is then used to drive improvement. An effective system allows key messages to be cascaded into the organisation in a suitable form and thus ensures that the 'right messages are received by the right people at the right time';
- The enabling of processes and systems which ensure that risks are properly assessed and reviewed and that this is done in such a way that independent challenge is welcomed, that learning is encouraged and shared and that there is clarity about priorities backed by adequate resources. When actions are taken to address risks, it is essential that leaders confirm that these have been satisfactorily implemented;
- An awareness by leaders of the process safety risks which they are managing and a recognition that when commercial and other pressures require organisational changes to be made, this is done after carefully considering the effect on these risks and adequate resources are available to manage them.

3.2. Operational attitudes and behaviours

Analysis of the events studied has provided many examples of issues which are brought together under this broad heading. This area relates to the safety culture at operational level and is strongly influenced by the strength of commitment of leaders - from those at the top of the organisation to middle managers and those with a front-line supervisory role.

— The need for effective procedures (which reflect risk assessments and/or safety case findings). In many events studied there was a failure to comply with procedures – in particular, a failure to distinguish between 'what is written and what is done'. This led to 'workarounds', violations and/or the development of informal procedures;
— It is important that operators have a sufficient understanding of the risks that procedures and instructions are designed to control. In some cases, the workforce had not received sufficient training on the risks (and particularly potential consequences) and there was a false belief that the control of industrial safety risks (e.g. slips, trips and falls) would necessarily lead to good performance across the spectrum of safety risks;
— Significant attention needs to be given to the role of first line supervisors in both setting standards and challenging unacceptable practices. In many of the events studied, this vital role was neglected - either because of the absence of supervision or because those carrying out the role were not sufficiently competent;
— A key identified issue is the need to encourage a questioning attitude and constructive challenge. In some cases, a failure to question resulted in important risks being 'normalised' and risks being taken on a habitual basis by default. In such cases, risks which were once identified as significant and worthy of particular attention became neglected because they had not led to major problems, although the risks had not reduced;
— The need to ensure that there is 'conservative decision making' such that process safety issues are always given sufficient attention and priority. This is particularly relevant in cases where novel processes are being used or in the case of 'new plant culture' – the view that a new plant or process at the cutting edge of technology is less likely to fail. It can also be important, however, where a process has become familiar and operators are no longer sufficiently cautious;
— Failure to address issues of complacency/overconfidence often arises from a view that the organisation has 'always done it this way'. In some cases the organisation had previously been successful but unrecognised organisational drift then led to degraded performance. Good performers do not always stay good performers;
— Communication issues have been a precursor to most of the events studied. Breakdown of communication occurred at shift handovers, between engineering or specialist support and operational staff, or with- and between- contractors;
— An important issue is the need for individuals and teams to be involved in identifying improvement opportunities and 'challenging' poor standards and actions. In some of the events studied, trust and involvement had been degraded by the lack of visible action and, perhaps understandably,

complacency had developed among those at the 'sharp end' in their commitment to reporting shortfalls in procedures, faulty equipment or 'near hits';

— Providing sufficient capability in recognising and dealing with abnormal events and/or recurring issues was highlighted by several of the events studied. This was exemplified in some events by a failure to understand the significance of alarms, to deal with information overload and to seek assistance when issues had escalated beyond normal operations. It is suggested that operational staff need clear training and guidance on when to stop and seek expert advice;
— The development of inappropriate patterns of work with casual transfer of roles and in some cases the working of long hours leading to fatigue and possible deterioration in the ability to make important decisions.

3.3. Business environment

Nearly all of the events studied arose against a background of significant commercial and/or operational pressure. In any organisation there is always a balance to be struck between the pressures of production/delivery and the achievement of acceptable levels of safety performance. It is when the balance leans towards achieving commercial results at the expense of safety that danger arises. The following are among the specific issues which have been identified:

— The process safety implications of changes to the organisation in terms of either people or other resources need to be consistently recognised. Problems have sometimes arisen because required changes were perceived as urgent and on other occasions because there was insufficient analysis to make leaders and managers aware of the implications of the change;
— In some cases, business decisions from ‘above’ overburdened plants so that they were overloaded with initiatives and requirements. This led to a loss of direction and sense of priority. More specifically, personnel regarded new requirements on them merely as ‘flavour of the month’ and commitment and trust was lost. Loss of direction was sometimes exacerbated in cases where there were very rapid changes in the composition of the leadership team and poor succession planning - leading to inconsistency of message and changed priorities;
— In organisations where resource reductions become the norm (e.g. cost cutting in continuing attempts to restore profitability in the face of changing market conditions), ‘salami slicing’ of resources had taken place without the review of the cumulative impact of such changes on process safety;
— Where new facilities are acquired, this can lead to positive steps to improve the material condition and people-related issues at the facility. Sometimes, however, the fact that infrastructure is in a relatively poor state was not

fully recognised and acted upon, and in some cases was allowed to deteriorate further, with new owners unwilling or unaware of the need to seek substantial improvement;

— Commercial and 'political' pressures have led to organisations outsourcing or passing substantial safety related responsibilities and competences to contractors often in order to minimise costs. This has to be treated with care in a process safety context since it can result in a loss of clarity about accountabilities, a failure of the contracting organisation to maintain its competence as an informed and intelligent customer and in some contexts, to abrogate its responsibilities as a licensee/duty holder;
— Incentives have sometimes been introduced which fail to take account of process safety issues and which concentrate primarily on financial or quality-related issues – sometimes with a negative impact on safety. Where incentives are introduced, it is important to examine the potential impact of these and introduce balancing requirements or other incentives to give safety sufficiently high priority;
— Changes in the business environment led in some cases to processes or plant becoming neglected with a significant impact on process safety. The 'orphan plant' issue, as exemplified by the Tokai-mura accident, illustrates the potential of this as a factor in events. In this case there was an apparent lack of 'ownership' of a peripheral plant which was not in the mainstream of the organisation's business. A similar issue relates to 'organisational drift'. In this case, a once 'high performing' plant deteriorates and standards drop, whilst leaders and regulators fail to notice, and continue to act as though the plant has retained its previous high standards.

3.4. Organisational learning

For most of the events studied there had been previous events from which there was suitable learning available. If this had been acted upon, the event probably would not have occurred. We observe that following events (not just in safety but in other areas of public concern), great emphasis is placed on the learning that has emerged and in the need for it to be acted upon but it is not clear as to the extent that this is achieved in practice. Although there is an asymmetry in the process, in the sense that successful learning is rarely demonstrated because 'no event is a non event', there appears to be a need to investigate how effective learning is best achieved. The following issues were among those identified:

— There is a need for an effective system for event reporting particularly in relation to process safety. Reporting was poor in many cases, for a variety of reasons, including apparent concerns from staff that their reports would not be part of a 'just' or 'blame free' response, would add to already high work load, that bad news would not be welcome at more senior levels, that there was insufficient knowledge to recognise precursors and/or that there was simply a culture of mistrust or complacency which did not encourage open reporting;

— Previous events had not been investigated on a systematic basis. This was reflected in a failure to investigate some events at all, and in other cases there was a failure to consider deeper root causes. Learning from events was often not shared within the organisation or beyond, as part of an effective feedback programme;
— In most cases there were historical events which provided significant learning opportunities. Some of these had happened in the organisation and others were from companies within the same industrial sector. Rarely was the relevance of wider inter-industry learning appreciated. Where learning opportunities had been recognised, they had often faded in significance within the corporate memory or improvement actions taken had not been tracked, completed or carried out effectively. They were often not embedded in training and team reviews;
— The development of 'organisational silos' can also lead to important knowledge which might have minimised the risk of the resulting event not being adequately transferred within the organisation. There was, for example, a failure to transfer learning between engineering or technical staff and operations staff, or to share learning with contractors.

4. USING THE FINDINGS

The next question is how these findings might be formulated in such a way that operating organisations and regulatory bodies might use them to assess the extent to which they have been recognised. As a starting point, a series of positive statements in the form of 'objectives' or 'expectations' were generated which built on the above findings. For each of the major findings, about twelve such statements were developed. Recognising the importance of these was considered to be an important first step in reducing risks, but the expectations do not themselves provide sufficient confidence that the organisation achieve them in practice. The next step was thus to take each of the statements and formulate simple yet testing questions that might enable an assessor to find out whether the organisation 'lives' the expectations in practice. Currently, the 'probing' questions are being further developed and tested with industry to enable assessment of the extent to which 'objectives', once recognised, are being met in practice.

It is argued that the use of the expectations, together with the more 'probing' questions, would allow an operating organisation or a regulatory body to get a much stronger feel for the vulnerability of the organisation to organisational accidents. This could be done generically across all of the identified issues or could concentrate on one or two areas where there was a greater perceived vulnerability. It has been pointed out that accepting the challenge and being prepared to ask these difficult questions, might itself give a good indication of the safety 'maturity' of an operational organisation!

Our work, so far, has indicated that assessing expectations arising from the 'real' events studied and comparing them with current corporate or business group internal policies or objectives has been of significant interest to our industry partners in this and proposed further research [27, 28]. Developing a more systematic process to assess vulnerability (systematic condition monitoring) which incorporates the expectations and question sets has also been seen as valuable. Various approaches are being investigated. Among the most promising of these is the use of Hierarchical Process Modelling (HPM).

5. HIERARCHICAL PROCESS MODELLING (HPM)

HPM provides a detailed understanding of the top-process (i.e. the highest level process that defines the purpose of the activity) in terms of the factors that lead to the success of that process. The hierarchy elaborates these factors in increasing levels of detail. This improves transparency by enabling stakeholders to 'walk through the model' and understand how lower level processes affect the performance of higher level processes. It thus introduces a systematic approach to the analysis of the issues and the opportunity to prioritise much in the same way that probabilistic risk assessment (PRA) achieves this in a more conventional engineering context. It is not recommended that users of HPM should attach numerical indicators to the results as there will be a substantial degree of judgement in 'scoring' the answers even when using the detailed questions as a source for input. However, the use of 'traffic lights' or similar approaches such as 'Italian flag' indicators [29] can be useful in formalising and reaching consensus on judgements. The output from the HPM can then be used to identify priorities for improvement.

In an earlier publication by the present authors (10), 'Organisational learning' was broken into four sub-processes. The first of these covered the ability of the organisation to identify and retain the learning from events. The second dealt with the capability to communicate this learning more widely within and beyond the organisation. The third sub-process reflected the ability of the organisation to 'keep the learning alive' so that it has continuing usefulness. The final sub-processes at this level reflected the need to ensure that actions are taken as a result of the learning, and that their effectiveness is monitored.

The first of these sub-processes was then followed deeper into the HPM, drawing on the expectations and questions derived for this topic. Thus the need to identify and retain on a systematic basis the learning from events, requires consideration of the following: a) past events from within the organisation and from outside, and b) learning from new events within the organisation as they occur. This second sub-process was further divided into the need to have effective processes for the reporting of events inside the organisation and for their investigation. The bottom level of the HPM uses the statements and questions illustrated above, to obtain evidence on the effectiveness of the internal reporting and investigation processes.

6. SYSTEM DYNAMICS (SD)

As discussed above, the statements/questions elicited in the HPM are rarely independent of each other. If organisations are to act on the outputs, therefore, it is important that tools are available which take a 'systems view' and allow the interactions, interdependencies and dynamic effects to be recognised and assessed before change processes are initiated that could lead to unconsidered and unwanted consequences. Dealing with complexity was highlighted in findings from the IAEA investigation into Fukushima [30]. System Dynamics provides an approach which shows promise in addressing this important issue.

The first stage of building an SD model is usually the construction of a causal loop diagram. These are directed representations of the influence between variables. The variables are visually depicted with labelled arrows representing their interactions. A '+' labelling indicates a positive relationship where the value of the 'child' variable changes in the same direction as the 'parent', whilst a '-' represents an inverse relationship (i.e. a decrease/increase in the 'parent' variable would lead to an increase/decrease in the 'child') .

A particular strength of SD is in drawing out potentially 'hidden' consequences of what might first appear as straightforward interventions to improve performance. It does this by modelling at a lower level of abstraction. For example, the inclusion of feedback allows aspects of non-linearity to be modelled directly (cf. HPM). In SD, causal feedback loops capture the complexity present in some processes, explain why consequences can be subtle or hidden, and demonstrate long term trends. These loops can also model the lags in response to actions. In Fig. 2 below, a simple example is shown relating to one potential issue drawn from the findings, expectations and associated questions sets relating to Organisational Learning, but in the context of the dangers of leaders and senior managers failing to appreciate the day-to- day implications of their decisions on staff at operational level.

In almost all of the events studied, there has been a strong 'disconnect' between the knowledge and aspirations of senior management and those planning and carrying out operations. There has, for example, frequently been a failure to ensure that information flows up and down the management chain are effective. It has often led to conflicts between the need to maintain safety standards through exercising a cautious and questioning attitude in the light of uncertainty and the need to meet production and cost targets. Business pressures have led to shortcuts, failure to provide sufficient oversight so that leaders are aware of the true picture of process/nuclear safety at operational level (often leading to organisational 'drift') , normalisation of risks, and the establishment of a 'good news culture'. Development of this 'disconnect' and its consequences have been shown to be interdependent, dynamic and complex.

The evolution of this 'disconnect' can be clearly seen when an SD approach is used to consider the possible consequences of management actions and exhortations to increase the number of near misses or process safety shortfalls (learning opportunities) being reported. The right hand loop shows that more reporting will lead to more investigations and thus to more corrective actions. Unless carefully controlled, prioritised and resourced, this may lead to a significant increase in the workload and as this increases, the fraction of completed actions and resulting improvements may go down. This, in turn, can lead to disillusion, complacency, reduced reporting in future and, in particular, a loss of faith by the workforce in the commitment of managers and leaders to the improvement process and reduced ‘buy-in’ from those who might report these learning opportunities. This will then run counter to the endeavours of management to encourage the workforce to increase the level of reporting as exemplified by the left hand loop in the figure. Thus even this simple model in Fig.1, ties together many aspects raised by the events and captured by the expectations and questions. It suggests a level of complexity in the processes determining the ‘Number of Learning Opportunities Reported,’ which might be overlooked in a simple management initiative, yet has a clear influence on the vulnerability of an organisation. It points to the need to explore performance indicators arising from a change process which may not always be the most obvious - in this case 'number of reports raised' may not tell the whole story.

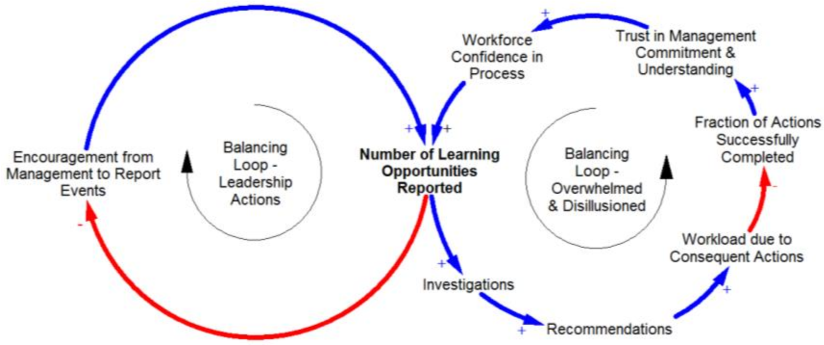


FIG. 1. Causal loop diagram illustrating the implications of attempting to improve reporting of learning opportunities without considering the full consequences.

A further example of the use of SD relates to rather more complex interactive issues relating to the management of contractors. About half of the above events had to various degrees, failures of contractor management and these exhibited many common features. Issues recognised included the following:

— A gradual loss of control with more and more responsibility being ceded to contractors and without the contracting organisation always being aware of its failure to retain the necessary control. In some cases it was

wrongly assumed that others were taking responsibility and acting on issues, when in reality they had fallen into the gaps in accountabilities;
— The contracting organisation sometimes lost competence (or failed to develop the necessary competence) and was thus unable to determine whether the contractor was carrying out its operations safely and/or with an acceptable safety culture;
— In some cases the contractor was more aware of an emerging issue than the contracting organisation. However, failures of communication, a lack of competence or commercial and other pressures, meant that advice from the contractor was not acted upon;
— Contractors were in some cases the subject of contracts which did not properly reflect the importance of safety as part of their role. Incentives to complete on time and to cost were frequently important drivers in failures to respond to 'danger signals' and ambiguities about the cost implications of reporting and responding to identified problems sometimes reinforced this.

We have taken the findings identified and held a workshop with industry and regulatory representatives to consider how the learning could help generate a more systematic approach to contractor management. The research has suggested that if the risk of major events is to be minimised, four basic elements in the overall contract management process need to be addressed. These are:

(a) Strategic Contractual Requirements.

These constitute the high level organisational requirements/policy, approved at a senior corporate level (e.g. Executive/Board) and contain the 'expectations' or prompts for the high level scrutiny of all proposed contracts with the potential (if not adequately managed) for significant safety-related consequences;

(b) Contract Management System (CMS - often part of a QMS or SMS)

This puts key issues into an operational context and identifies those that must be addressed in establishing a supply chain contract and, in particular, sets out the principles and systems that must be applied to manage the safety risks involved;

(c) Operational Phase Management Process

This defines the actual required management arrangements for a specific contract and how these might be managed to meet the CMS requirements;

(d) Independent Audit, Review and Oversight

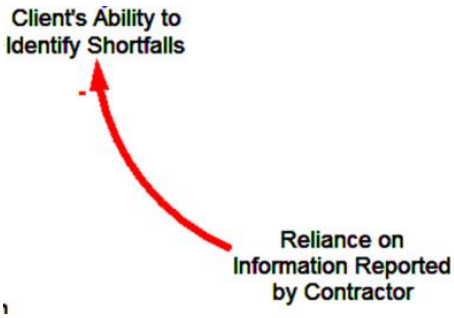
This element provides continued assurance that all of the above are meeting requirements and being exercised effectively to minimise risk as far as is reasonably practicable.

Within each of these elements, issues have been identified, the interactions between which are informed by an SD analysis. An outline example is now presented which derives from preliminary discussions in the workshop.

Participants were asked to consider the key variables involved in contractor management scenarios, the ways in which these variables could be affected, and the ways in which these variables could affect other processes. This resulted in a series of causal statements such as “improving X would lead to an improvement in Y”. These were combined with similar causal statements identified from the original accident investigation reports.

Table 1, below, illustrates the approach in a straightforward way and to show how a model can be constructed from simple building blocks into a more detailed process map which draws out the causal relationships involved. The left hand column contains ten statements describing, in generic terms, the narrative based on several historic events. The right hand column shows how this narrative can be represented visually as causal chains comprised of variables and labelled arrows.

TABLE 1. VISUAL REPRESENTATION OF CAUSAL STATEMENTS

<table>
<tr><th></th><th>Description/Causal Statement</th><th>Model Representation</th></tr>
<tr><td>1</td><td>Increased ability to identify weaknesses in a contractors work will lead a client to identify more safety concerns.</td><td>
</td></tr>
<tr><td>2</td><td>A larger number of safety concerns will drive a client to undertake more oversight of a contractor</td><td>
</td></tr>
<tr><td>3</td><td>A greater level of oversight will reduce the need to rely on reports from the contractor</td><td>
</td></tr>
<tr><td>4</td><td>Increased reliance on information reported by the contractor (meaning at the expense of other sources), reduces a client’s ability to identify weaknesses in contractor’s work</td><td>
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Combining the statements in the table above can reveal the formation of feedback loops (see Fig. 2 below) and complex systems of interacting processes.

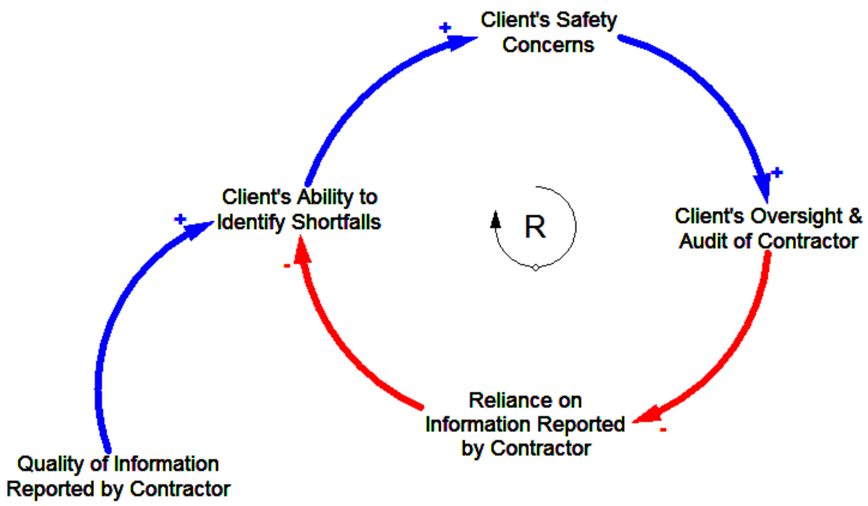

FIG. 2. Reinforcing feedback loop constructed from causal statements.

In a similar way the following statements from the workshop are all represented in the model below.

— Because of the client’s commercial risks and pressures, they may issue a request for tenders with unrealistically short timescales;
— Potential contractors do not challenge the timescales because they desire to win the contract;
— This can cause both parties to accept a project timescale with limited achievability;
— Upfront contract discussions and arrangements (such as competence requirements, safety case/risk assessment and management of change requirements, reporting routes and project interfaces and progress reviews/oversight) are not properly considered as a result of the short project timescales;
— Any design and safety case issues arising during the project (the initial causes of which can be considered to be outside the current model) will cause concern within the contractor’s project team;
— The contractor minimises these (with or without the approval of the client) and deals with them either through an approved process which will add to project delays, or alternatively, on an ad hoc basis in order to avoid or minimise delays;
— Whether or not the contractor seeks approval from the client is also affected by the initial consideration of communication requirements and the achievability of the accepted project timescale;

- The consideration of communication requirements and propensity towards ad-hoc, unplanned and unapproved modifications can impact the client's knowledge of the safety issues;
- The client's knowledge of the safety issues affects their ability to fulfil the role of 'Intelligent Customer' which can ultimately lead to changes in the relationship and trust between them and the regulator;
- The realisation of the key staff that short cuts/non- conservative decision making is being approved is likely to lead to a further deterioration in safety culture with a view that management condones this;
- If the safety 'fixes' do not lead to delays or more serious impacts during the contract, there may be longer term implications for the client.

Despite being the discrete linkage of two variables, when the statements are combined, they reveal a network of interactions and feedback loops that are not initially apparent. Thus Fig. 4 is nothing more than a visual depiction of the statements above.

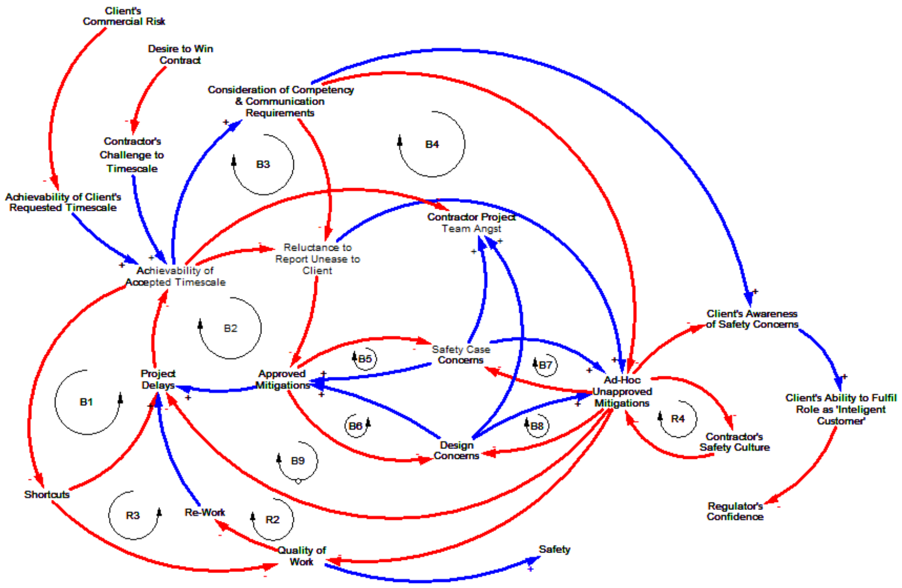

FIG. 4. A preliminary SD model addressing some key issues in the management of contractors composed from the above statements and based on learning from some of the events studied.

At first this may seem complex and hard to interpret, but models such as this can be used to identify important feedback loops, trace the underling complex structures of causality which produce the observed behaviours and pinpoint key leverage points where important variables can be monitored or new corrective actions taken. Nine loops which resist change and work to find an equilibrium (known as balancing loops) are highlighted, along with five loops which reinforce and speed up the effects of any changes. These types of relationship are not normally made explicit in this way. Both types of feedback loop can be positive or negative. Trying to make changes to a situation with a balancing loop by only adjusting the variables will not work - the feedback structure itself needs to be considered. Similarly, new balancing loops could be built into the system to compensate for unwanted feedback loops which reinforce negative behaviours.

From the above preliminary model then it is possible to identify two key leverage points which have significant impacts on the dynamics of the system and the observed behaviours. Firstly, the achievability of the accepted timescales. This variable can be controlled at the inception of the project, and if a timescale with low achievability is accepted, this can set in motion a series of behaviours that could ultimately have negative impacts. A mechanism to ensure the timescale is achievable and realistic would reduce the probability of the subsequent actions and emergent behaviours. It also draws out the importance of ensuring that the management system addresses the adequacy of communication requirements and makes sure in practice that these are understood (along with the mechanisms for approving deviations from the original plan).

7. CONCLUSIONS

Research into the organisational and cultural precursors to twelve major events across a range of industry sectors has shown that these are strikingly similar. The findings from the analysis were categorised under eight headings and examples of these are given in the paper. In each case, these were first translated first into statements in the form of 'objectives' or 'expectations' which could be compared by industry and regulators with their existing corporate or regulatory requirements for excellence in process safety. It is reassuring that many of these high level 'objectives' align with the findings on safety culture contained in various documents developed by the IAEA (e.g. 31 and references therein)

These were then, in turn, translated into sets of draft penetrating questions which have begun to be trialled with industry. They allow 'condition monitoring' to be carried out to assess the extent to which organisations are transferring their aspirations into operational reality.

It is possible that this analytical approach will be relevant to events outside the engineering industries - for example, breakdowns in financial and social systems. This may be an interesting area of future potential research. Another area of potential interest is that of understanding better some of the influences and behaviours from a social sciences perspective (i.e. what human and organisational factors influence the making of particular, sometimes critical, decisions) and our planned further research involves social scientists in order to consider the human and organisational 'influences' which lead to behaviours in different situations. Furthermore, when future inquiries are carried out into accidents or significant near misses, the issues recognised here might provide a useful check list for deepening the analysis into the organisational and cultural precursors which may have been important factors in the event.

This initial approach to the analysis and use of the events proved useful, but by analogy with the systematic approach used for engineering and human factors based vulnerabilities, work has begun on developing a similar systematic approach for examining these organisational and cultural precursors. An example has been shown which demonstrates the utility of the approach in aspects of 'organisational learning'.

The research has drawn out the need to examine issues of interdependence and complexity in treating the precursors. To this end, the technique of System Dynamics is now being used to develop prototype 'flight simulators' which allow these important interactions to be understood and assessed before changes are introduced which may lead to unintended consequences. The technique enables performance indicators to be adopted which may provide greater insights into the impact of change than the more obvious indicators that are often chosen. Two examples have been given of the approach. The first is relatively simple but deals with one aspect of 'disconnects' between leadership and those carrying out day-to-day operations in the context of management attempts to improve the reporting of 'events', near misses or operational shortcomings. The second shows preliminary results from a wider initiative to use the learning from events which arose from shortcomings in contractor or supply chain management as an input to develop better management processes. System Dynamics has been used in this case to examine the impact of inadequate front end contract planning and considers the potential consequences of this

ACKNOWLEDGEMENTS

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EVOLUTION OF RADIATION SAFETY CULTURE IN AFRICA: IMPACT OF THE CHERNOBYL ACCIDENT

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Abstract

The use of ionizing radiation in Africa is more than a century old but the awareness for radiation safety regulation is still work in progress. The nuclear weapon tests carried out in the Sahara Desert during the early 1960's and the resultant radiation fallout that drifted into West Africa with the north-easterly winds provided the first organized response to the hazards of ionizing radiation in Nigeria. The Nigerian Government in 1964 established the Federal Radiation Protection Service (FRPS) at the Physics Department of the University of Ibadan but without the force of law. In 1971, draft legislation on Nuclear Safety and Radiation Protection was submitted to Government for consideration and promulgation. It never went beyond a draft until June 1995 only after IAEA intervention! The April 1986 Chernobyl nuclear accident unfortunately did not provoke as much reaction from African countries, probably because of geography and climate: Africa is far from Ukraine and in April the winds blow from SW-NE, unlike if it had happened in December when the wind direction would have been NE-SW and Africa would have been greatly impacted with little or no radiation safety infrastructure to detect the radiation fallout or to respond to it; and weak economic infrastructure to mitigate the economic impact of such radioactive deposits on agriculture and human health. Africa was shielded by both geography and climate; but not for long. By 1988, some unscrupulous businessmen exported to Nigeria and to several African countries radiation contaminated beef and dairy products which were meant for destruction in Europe. This led to the establishment of laboratories in several African countries for the monitoring of radiation contamination of imported foods. Fortunately, the international response to the Chernobyl accident was swift and beneficial to Africa and largely spurred the establishment of radiation safety infrastructure in most if not all African Member States. Notably amongst the IAEA interventions towards the establishment of radiation safety infrastructure are the RAPAT missions and the Model Project on "*Strengthening Radiation Protection Infrastructure"*. The Model Project (1994-2004) aimed at assisting Member States in meeting the requirements of the international basic safety standards. The Model Project achieved a lot but its closure in 2004 compelled regulatory bodies in the Africa to search for alternative mechanism for building on the success of the Model Project and find ways and means of expanding the scope of the Model Project but without the sole sponsorship of or promotion by the Agency by taking ownership of radiation safety infrastructure in their countries. This resolution led to several discussions and consultations among regulatory bodies in the region which culminated in 2009 into the formation of the *Forum of Nuclear Regulatory Authorities in Africa*. The IAEA RASSIA Missions and the IRRS Missions provide the opportunity to peer-review the radiation safety infrastructure and promote continuous improvement. The ultimate goal of all these efforts is the emplacement of a sustainable radiation safety culture, which is a fabric that can be woven with different fibres: legislation, institutions, manpower, national and international support, etc. Development of radiation safety infrastructure in Africa and indeed the evolution of the radiation safety culture in the region is indeed work in progress.

1. INTRODUCTION

In Africa today, there is an increasing use of sources of ionizing radiation and radioactive materials in various socio economic development activities. The growing application of radiation and nuclear technology is widespread, ranging from health and agriculture sectors to the petroleum sector and manufacturing industry. The application of nuclear technology is rapidly expanding to other areas, including uranium mining and milling, research reactors and recently there is an expressed interest by member states to pursue nuclear options for power generation. These developments are driven by the global economic, technological, social and environmental factors and the concomitant increase of awareness and recognition of the beneficial role of nuclear technology in the development of the African continent's socio-economic landscape. The change is also witnessed by the increased technical cooperation activities between the International Atomic Energy Agency and members states in the African region.

In the early 1960's, nuclear weapon tests were carried out in the Sahara Desert, which resulted in radiation being drifted into Nigeria with the north-easterly winds. In reaction to this development, the Federal Government in 1964 established the Federal Radiation Protection Service (FRPS) at the Physics Department of the University of Ibadan. The FRPS was established without an Act of Parliament and therefore lacked the powers to regulate and control the use of nuclear radiation. In 1971, a draft decree on radiation protection was proposed by the FRPS and sent to the then Federal Military Government for consideration and promulgation. It never went beyond a draft. On the 24th August 1976, the Federal Military Government enacted Decree No. 46 (now Act), which established the Nigerian Atomic Energy Commission, (NAEC) [1]. This became the very first legislation by any government in the federation towards the orderly and safe use of nuclear energy. According to this Act, the Commission was entrusted with the responsibility for the development of atomic energy and all matters relating to its peaceful uses. The Nigeria Atomic Energy Commission Act was not intended to regulate the use of nuclear radiation but rather to promote and increase its use. The decree led to the establishment of the two nuclear energy research centres at the Ahmadu Bello University, Zaria and at the Obafemi Awolowo University, Ile-Ife. The two research centres acquired very sophisticated and powerful nuclear research equipment and machines, including a nuclear reactor, a particle accelerator and neutron generators. In early 1988, Nigeria experienced a situation when some unscrupulous business group exported industrial waste into Nigeria through a port in the Niger Delta, Koko port. The two research centres were then commissioned to analyse the imported industrial waste for radioactivity and elemental composition, a task they performed creditably well [2]. This single incident led to the promulgation of a decree banning the importation of waste into the country and this ultimately resulted into the enactment of another legislation, the Federal Environmental Protection Agency Decree No. 8 of 1991(now Act) [3] and consequently the establishment of the Federal Environmental

Protection Agency (FEPA). Fortunately, a pleasant “Koko” incident actually did happen in the Nigerian nuclear energy industry before a regulatory decree was promulgated. Under the auspices of the Energy Commission of Nigeria, the International Atomic Energy Agency (IAEA), Vienna approved to donate and install a nuclear research reactor in Nigeria. This was based on a Technical Cooperation Project proposal submitted by the Centre for Energy Research and Training, Zaria in 1993. The implementation of the project commenced in January 1995. The IAEA gave the Nigerian Government some pre-conditions for the implementation of the project, which included promulgation of a decree to regulate the use of ionizing radiation and nuclear materials in Nigeria. It was towards this end that the Centre for Energy Research and Training, Zaria held a National Workshop on "*Radiation Safety and the Nigerian Legal System*" in June 1995[4]. The Energy Commission of Nigeria (ECN) spearheaded the drive to persuade the then Federal Military Government to put in place a law that would regulate all peaceful applications of nuclear energy in the country. By August 1995, the Government promptly promulgated the *Nuclear Safety and Radiation Protection Decree 19 of 1995* (now Act) [5]. This single act facilitated the supply of the nuclear reactor to Zaria. The installation of the reactor was completed during the first quarter of 1999. It is pertinent to add that the same Federal Government invested a lot of resources to provide the buildings and other infrastructure for the nuclear reactor. The nuclear reactor could however not be commissioned because the law was not implemented. The Nuclear Safety and Radiation Protection Act provides for the establishment of the *Nigerian Nuclear Regulatory Authority*, but was not set up until 2001. This is a very typical experience with many countries in the region.

2. THE CHERNOBYL ACCIDENT

In April 1986 when the Chernobyl accident occurred, Nigeria has already well established nuclear research centres that had some capacity and infrastructure for carrying out training and research in areas of nuclear science and technology. In Nigeria, the news of the Chernobyl nuclear accident came through international news media as there was no routine monitoring of environmental radiation in many countries in the region, including Nigeria. At this same time many of us in Africa did not expect the Chernobyl nuclear accident to have profound consequences on us even though Africa and Europe are in the same hemisphere but geography separated Ukraine from the African countries. Furthermore, climatic factors and the time of the year provided another shield for many countries in Africa, but not for long. In May the winds blow from SW-NE, therefore the radiation fallout from the accident were first noticed by countries north of Chernobyl, unlike if it had happened in December when the wind direction would have been NE-SW and Africa would have been impacted with little or no radiation safety infrastructure to detect the radiation fallout or to respond to it. Courtesy of the British Council, the Centre for Energy Research and Training (CERT) at the Ahmadu Bello University, Zaria organized a one day National

Symposium on the Chernobyl Nuclear Accident on 26th May 1986. The British Council facilitated the participation of two experts from two different universities in Scotland. This was very instructive and educative to the university community. But by 1989, some unscrupulous businessmen exported to Nigeria radioactive contaminated beef from Europe which was supposed to have been destroyed. Mercifully, the shipment was arrested and the consignment destroyed. This was at a time that most if not all African countries had very weak radiation safety infrastructure and of course non-existent nuclear safety infrastructure. That was 30 years ago.

3. THE NATIONAL RESPONSE

The Zaria symposium of May 1986 provided the strongest impression on the university community about some the consequences of nuclear power. The news about the importation of radiation contaminated beef into the country heightened the awareness of the entire country about the impact of a nuclear accident in a one part of the world could have on far away locations as it is the case between Nigeria and Chernobyl! This became even more impactful by the directive of the Federal Military Government that CERT should analyze the contaminated beef imported into the country. Using IAEA standards and procedures, CERT was able to show that the imported beef had about three times the concentration of Cessium-137 than the Nigerian beef and more than the IAEA standards but less than the maximum permissible concentration. Upon submission of this report [6] to Government, a decree was promulgated the same day prohibiting the importation of beef and poultry products into Nigeria. This was subsequently followed with another decree [7] establishing the Food and Drug Administration Control which had been hitherto been in draft form. The pending draft legislation on nuclear safety and radiation protection however remained a draft. But the nuclear research centres however received a tacit recognition of their competences and capability! The Nuclear Safety and Radiation Protection Act was however not promulgated until 1995 and implemented only in 2001.

4. INTERNATIONAL RESPONSE

Since the Chernobyl nuclear accident the IAEA carried out several missions to Member States in the region, such as WAMAP, RAPAT, both of which provided some assessment of radiation safety infrastructure in Member States. In mitigating the challenges posed by the radiation safety infrastructure deficits, the IAEA in 1994 embarked on a systematic provision of assistance to Member States to establish and strengthen their radiation safety under the umbrella of a ‘Model Project’.

The Model Project Approach (MPA) is one of the three principal tools the Agency has deployed at achieving its strategic objective, which has been severally described as partnering with Member States to ‘achieve productive and sustainable human capacity building in nuclear institutions. To this end the technical cooperation with the Member States is directed at promoting "tangible socio-economic impact by contributing directly in a cost-effective manner to the achievement of the major sustainable development priorities of each country". The MPA addresses the setting and maintaining of standards of quality in project design, with the ultimate beneficiaries as its target, i.e. not the beneficiary institution but the general public. The MPA necessarily requires detailed work plans and objective performance indicators. Model Projects must therefore:

(a) respond to a real need of the developing country;
(b) produce significant economic or social impact through the end user;
(c) reflect the distinct advantages of nuclear technology over other approaches;
(d) attract strong government commitment; and
(e) demand direct involvement of the sector involved

In addition to several inter-regional, regional and national TC projects, the Agency in 1994 launched an Interregional Model Project on "*Strengthening Radiation Protection Infrastructure*". The main objective is not only to recommend but to work together, "shoulder to shoulder" with Member States, to eliminate the shortcomings in their safety infrastructure and control of radiation sources.
The Model Project is based on five Milestones set to meet the requirements of the BSS. It consists of comprehensive work plans with well identified sets of activities, the implementation of which mark the completion of a milestone. These are:

Milestone 1: *Establishment of Legislative and Regulatory Infrastructure*.
Milestone 2: *Establishment of Occupational Exposure Control Programme*
Milestone 3: *Establishment of Medical Exposure Control Programme*
Milestone 4: *Establishment of Public Exposure Control Programme*
Milestone 5: *Establishment of Emergency Preparedness and Response Programme*

The Model Project at its closure was found to be very successful in achieving its set objectives but not 100% successful; for it had the following advantages and disadvantages,

Advantages:

(a) Provides a holistic approach to the implementation of the BSS
(b) Prompt provision of assistance upon signing on to the Model Project
(c) Provides opportunity to learn from others in the region, through formal and informal peer review, thus leading to a push-pull mechanism, which cannot be achieved through national projects or even regional projects

(d) Creates a multi-task environment, in the sense that all the five dimensions are considered to be components of a whole.
(e) Reminds Member States of the nexus between safety and promotional activities, as was the case in Nigeria.

Disadvantages:

(a) Presupposes the existence of some level of radiation protection infrastructure;
(b) May not be very beneficial for Member States with very weak infrastructure;
(c) Demands a multi-task response in terms of human and material resources;
(d) Demands a lot of competences in areas related to all the activities in the Model Project

Following the closure of the Model Project in 2004 and the need to assist Member States in strengthening their Radiation Safety Infrastructure in a manner consistent with the BSS, the Agency again introduced a different approach that was based on the following Thematic Safety Areas:

TSA 1: Regulatory Infrastructure;
TSA 2: Radiological Protection in Occupational Exposure
TSA 3: Radiological Protection in Medical Exposure
TSA 4: Public and Environmental Radiological Protection
TSA 5: Emergency Preparedness & Response
TSA 6: Education & Training
TSA 7: Transport Safety

In addition there are several advisory missions to Member States with the objective of strengthening the national Radiation Safety Infrastructure. These include:

(a) Advisory Missions
(b) Integrated Regulatory Review Service Missions
(c) Occupational Radiation Protection Appraisal Service (ORPAS)
(d) Emergency Preparedness Review (EPREV)
(e) Waste Safety Appraisal Service
(f) Transport Safety Appraisal Service (TranSAS)
(g) Education and Training Appraisal (EduTA)

Furthermore, the Agency has developed several software tools and IT platforms to facilitate monitoring of progress in Radiation Safety Infrastructural Development. These include:

(a) Radiation Safety Information Management System (RASIMS)
(b) Self-Assessment of Regulatory Infrastructure for Safety (SARIS)
(c) Regulatory Authority Information System (RAIS)
(d) Control of Sources Network

In furtherance of the continuous improvement, in 2013, SAGTAC VI recommended at its second meeting yet another approach to the Director General: Strategic Approach with the objective to accelerate the establishment and strengthening of an effective radiation safety infrastructure through the development and implementation of a national strategy in a comprehensive, holistic, efficient and sustainable manner while making optimal use of national, regional and international resources. In spite of all of these efforts, there are still gaps and challenges that need to be addressed. The achievements and challenges recorded under the Thematic Safety Areas approach have been well documented in the Radiation Safety Information Management System (RASIMS). The results for the first four TSAs are shown in figures 1-4 below. It is in this regard, that there is the need for a strong regional platform that can effectively leverage the opportunities provided by the international community in general and the IAEA in particular.

TABLE 1. LEGEND EXPLAINING FIGURES BELOW

Color	Level of progress
(green)	Good progress
(yellow)	Medium progress
(pink)	Limited progress
(red)	Low progress

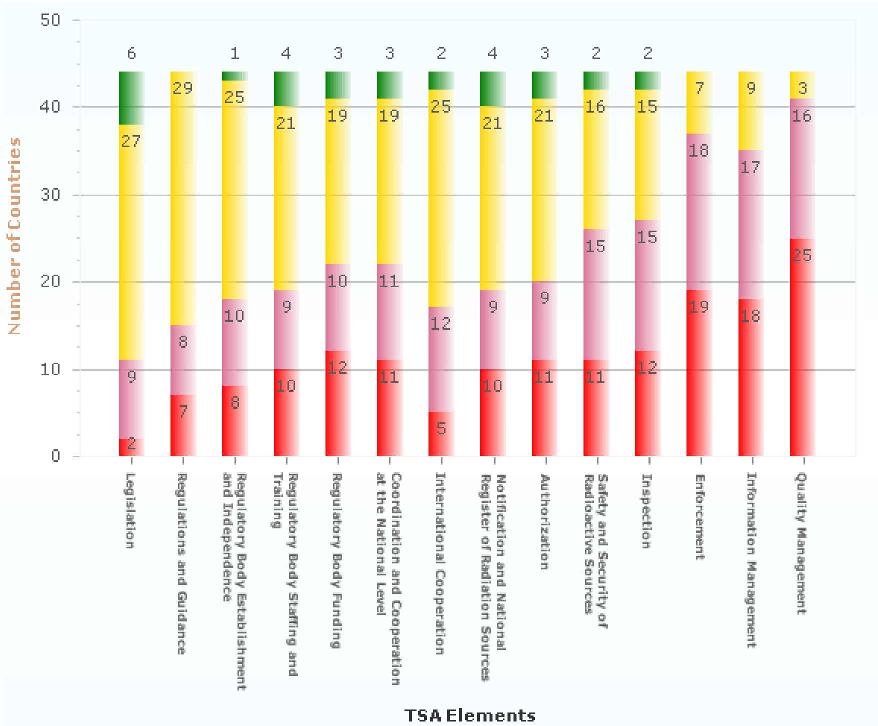

FIG. 1. Regulatory infrastructure (TSA 1).

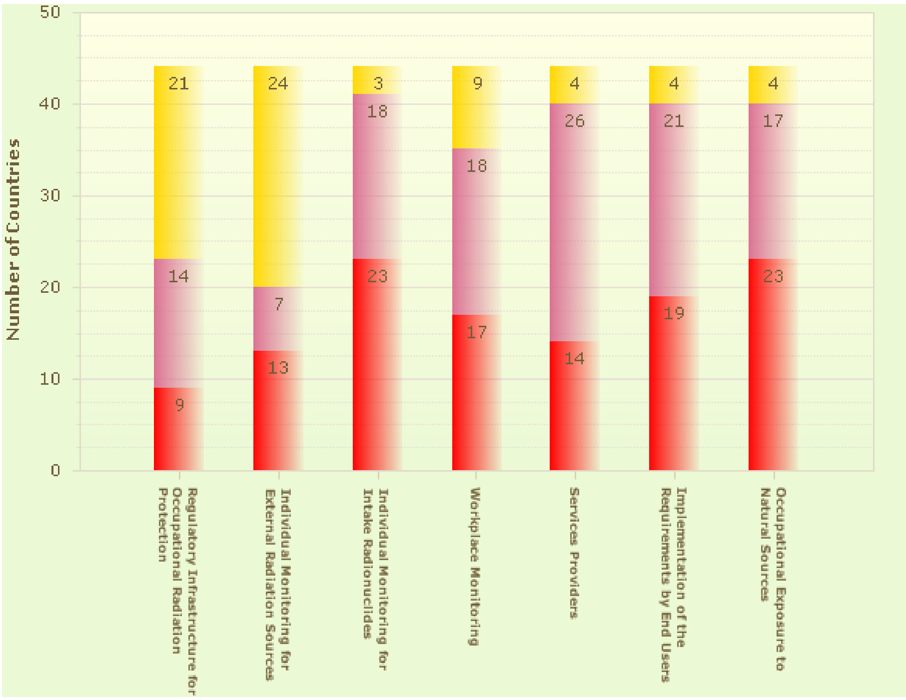

FIG. 2. Radiological protection in occupational exposure (TSA 2).

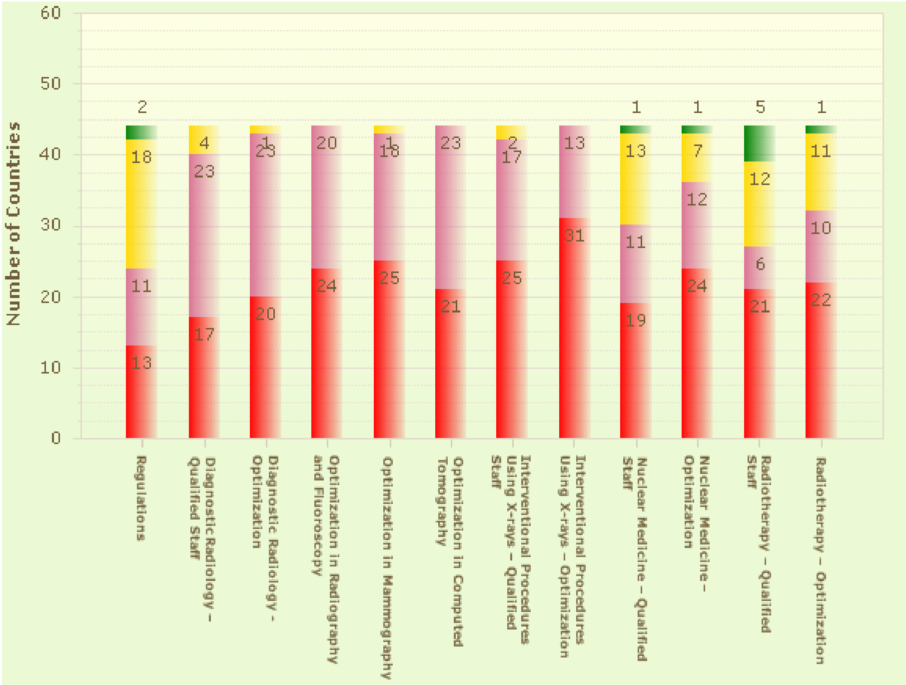

FIG. 3. Radiological protection in medical exposure (TSA 3).

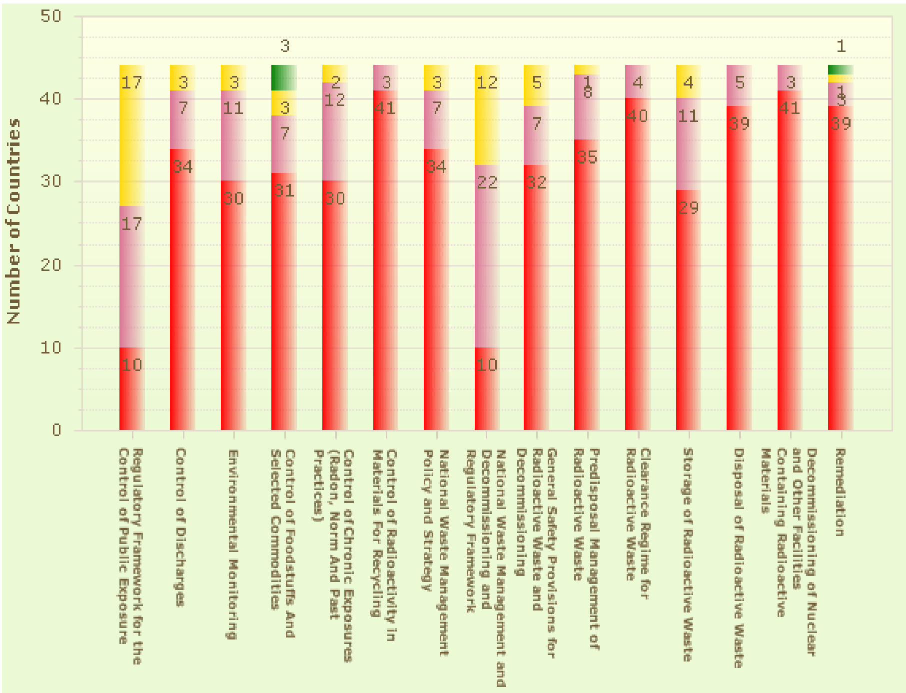

FIG. 4. Public and environmental radiological protection (TSA 4).

5. THE REGIONAL RESPONSE

In September 2004, the 48th IAEA General Conference, which coincided with the 50th Anniversary of its establishment, took a resolution to wind down the "Model Project" by changing its format from what it used to be at inception in 1994. The "Model Project" definitely achieved a lot in the ten years of its operation. This was difficult to accept but it marked the 'coming of age' of the Regulatory Authorities in the region, which therefore decided to search for alternative mechanism for building on the success of the Model Project and find ways and means of expanding the scope of the Model Project but without the sole sponsorship of or promotion by the Agency. In order words, can the African Member Sates take ownership of radiation protection and radiation safety because it is in our best interest to do so? This question led to several discussions and consultations among regulatory bodies in the region for about five years. Finally on Thursday 26th March 2009, twenty-nine regulatory bodies representing twenty-eight Member States resolved to establish the *Forum of Nuclear Regulatory Authorities in Africa*. The Forum has a nine-member Steering Committee representing all the five sub-regions of the continent and its activities are guided by a ***Charter*.** The Plenary is the highest organ of the *Forum* and it comprises of all the Heads of the Member Regulatory Bodies. Membership of the Forum is open to all Nuclear Regulatory Bodies in the region and it is voluntary. Today, there are 32 Member Regulatory Bodies in the *Forum*. The objectives of the *Forum* are to:

(a) Provide a platform for fostering regional cooperation;
(b) Provide for the exchange of expertise, information and experience;
(c) Provide opportunity for mutual support and coordination of regional initiatives; and
(d) Leverage the development and optimization of resource utilization.

In carrying out these objectives, the *Forum* identified seven thematic areas of interest that require immediate attention and action. Correspondingly, seven Technical Working Groups (TWG) were constituted to address those areas of need. These are:

TWG1: Upgrading Legislative and Regulatory Infrastructure
TWG2: Upgrading Safety in Radiotherapy
TWG3: Upgrading Safety in Uranium Mining and Milling
TWG4: Regulatory Framework for Licensing of Nuclear Power Plant
TWG5: Upgrading Safety in Nuclear Research Reactor
TWG6: Education and Training and Knowledge Management
TWG7: Upgrading Safety of Radioactive Waste Management Infrastructure

6. CONCLUSION

The establishment of the Forum of Nuclear Regulatory Bodies in Africa will remain a major step at consolidating the gains of the various strategies of the IAEA in strengthening Radiation Safety Infrastructure in Africa if the Member States through the African Union can mainstream radiation safety as nothing esoteric but a statutory responsibility of every state and of the region. With this development, radiation safety in Africa will graduate from being an “IAEA requirement” for technical cooperation to a culture for the protection of our peoples.

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HISTORICAL FOUNDATION FOR SAFETY CULTURE AND HIGH RELIABILITY ORGANIZATIONS

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Abstract

"Close examination of six case studies – Three Mile Island, Bhopal, Challenger, Chernobyl, the Herald of Free Enterprise, and the King's Cross underground fire – indicate that latent rather than active failures now pose the greatest threat to the safety of high-technology systems. Such a view is amply borne out by more recent disasters such as the Piper Alpha explosion, the shooting down of the Iranian airbus by the U.S.S. Vincennes, the Clapham Junction and Purley rail crashes, and the Hillsborough football stadium catastrophe." As James Reason implied in the classic study Human Error (1990), the understanding of the history of high-technology systems should guide the understanding of what is necessary to improve the future safety of those systems. With that in mind, the paper discusses the historical foundation for the concepts of nuclear safety culture and High Reliability Organizations. In this respect, the paper is not so much about what the concepts are as it is about why the concepts were created and why they are essential elements of providing safety for high-risk activities. The hope is that the remembrance of why these concepts are fundamental to the avoidance of disasters will encourage the consideration of whether the essential elements those concepts represent are still captured within organizations conducting high-consequence activities.

1. INTRODUCTION

So why should we care about the history of the concepts of nuclear safety culture and high reliability organizations? After all, these concepts were established 3 decades ago, and they have been studied and refined significantly since then. The simple answer is to remember what George E. P. Box said many years ago, "Essentially, all models are wrong, but some are useful."

Conceptual models help us understand how our safety systems work, decisions get made, and accidents occur. A model's true value comes in its ability to help us identify patterns that are beneficial or detrimental to the desired goal. Each model has a history; it was created to explain a particular set of observations from a particular situation. When applying models to new situations one should always consider appropriateness by reviewing the history.

[1] The views expressed herein are solely those of the author, and no official support or endorsement by the Defense Nuclear Facilities Safety Board or the U.S. Government is intended or should be inferred.

I want to focus this discussion on the three decades leading up to and including the founding of these two concepts, 1960 through 1989. There are many ways in which one can decide whether an accident is organizational in nature, what is an accident's impact on society, and what are the most significant lessons to be learned from an accident. I used three informal criteria for selecting the accidents that I have chosen to highlight in this paper, (1) relative magnitude of consequences among accidents within its time period; (2) the accident's apparent significance in the history of its industry or society; and (3) accidents that are frequently cited as case studies in organizational accident literature. Figure 1 illustrates the major accidents that occurred during this thirty year period, from which the accidents discussed below have been drawn.

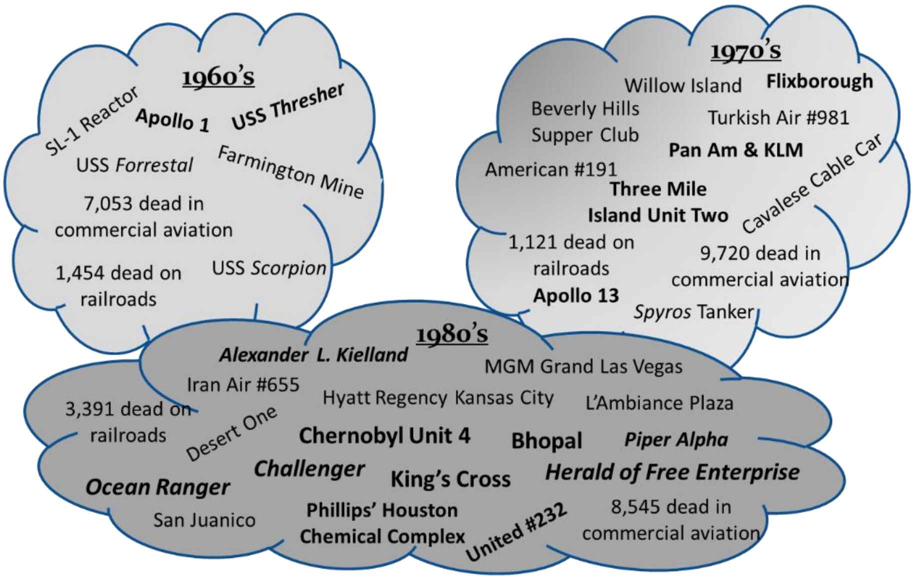

FIG. 1. Major organizational accidents that occurred between 1960 and 1989.

At first glance, it would appear that the rate at which organizational accidents occur is increasing from decade to decade, and there may be some truth to that. However, this increase also corresponds to a period when there was a very rapid expansion in society's dependence on technologies, products, and services that carry with them the potential for higher consequences should a failure occur. Therefore the higher numbers of accidents in later decades may be due to a higher number of risky activities and not an increase in the rate of accident occurrence.

What we do know about the concepts of nuclear safety culture and high reliability organizations is that they both are directly or indirectly rooted in nuclear reactor accidents. It is well known that the concept of nuclear safety culture came out of the IAEA's investigation into the Chernobyl Unit 4 explosion in 1986. The studies of high reliability organizations (HRO), human factors, human and organizational performance, all centered around the Three Mile Island Unit 2 meltdown of 1979. Therefore, I have chosen to develop the history of the two concepts with those two accidents as the centerpieces.

What becomes quickly apparent in reviewing HRO and nuclear safety culture literature is that Three Mile Island and Chernobyl were not the sole motivators of the two concepts. Instead, they represent seminal events, or tipping points, around which observations collected from previous accidents either coalesced into coherent understandings or were brought into the forefront of the discourse on safety in high-consequence activities. To demonstrate this coalescence of observations, I will walk through some of the accidents that occurred before and during the birth and early nurturing of the concepts of nuclear safety culture and HRO.

1.1. The foundational decade, 1960-1969

The history begins in January of 1961. On the third day of that month, the SL-1 reactor in Idaho was destroyed in a rapid power transient and all three operators were killed. The SL-1 was a prototype for a small power reactor designed to provide power at remote military bases. At the time of the accident, the operators were preparing the reactor for restart after a maintenance outage by reconnecting the control rods to their drive motors. This required an operator to withdrawal one control rod at a time about four inches to make the connection to its motor, and then to lower the rod back to the bottom of the core. This small of a movement should have had no effect on the reactor. However, during the movement of the central control rod the reactor went super prompt critical, creating a water hammer that destroyed the reactor so violently that all three operators died from traumatic injuries. Investigations into the accident concluded that for the power transient to occur, the operator had to have moved the central control rod about twenty inches. While the investigators were able to determine from the physical evidence what had initiated the event, they could never determine why the operator had deviated so far from what was necessary to accomplish the task. [1]

The interesting thing about the impact of this accident is that the debate about why the operator acted as he did continues to this day. While the simple determination of "human error" without further explanation was often accepted as sufficient explanation in most accidents, it was not accepted in this case. Since there were no survivors to explain what happened, the investigators were left in a quandary. While they could postulate situations where the action taken by the operator could have been inadvertent, there was insufficient evidence to support any of those situations. On the other hand, the opposite conclusion, that the operator had intentionally pulled the control rod out knowing full well what the consequence would be, was equally unacceptable without strong evidence to support it.

Two other accidents that occurred in the decade of the 1960s also helped to shape the understanding of safety in complex systems that underpins the concepts of HRO and nuclear safety culture. On April 10, 1963, the nuclear submarine USS Thresher was lost in the North Atlantic with all hands. The submarine was performing a test dive after a refit in the shipyard. Investigators concluded that the submarine had been lost due to a combination of design weaknesses and construction failures. This accident resulted in the birth of the Navy's SUBSAFE program, which has become a highly respected model for ensuring that safety is fully integrated into the design and construction of complex systems. [2]

On January 27, 1967, an American spacecraft suffered a flash fire during a pre-launch dress rehearsal for the Apollo 1 mission. All three astronauts in the spacecraft were killed. Contributing to the accident was both the spacecraft's design and the conditions imposed by the dress rehearsal. According to the U.S. Congressional Committee reviewing the results of the investigation,

No single person bears all of the responsibility for the Apollo 204 accident. It happened because many people made the mistake of failing to recognize a hazardous situation.

The test in process at the time of the accident was being conducted with a 100-percent pure oxygen cabin atmosphere at 16.7 p.s.i. and had not been identified as hazardous by responsible officials. However, one of the principal determinations of the Apollo 204 Review Board was that "the test conditions were extremely hazardous." The successful Mercury and Gemini programs both of which were tested and flown using a pure oxygen atmosphere and the hundreds of hours of successful testing with 100-percent pure oxygen apparently led to a false sense of confidence and therefore complacency in this operation. The committee can find no other explanation for the failure of the hundreds of highly-trained people on the Apollo program, including the astronauts, to evaluate the conditions under which the test was being conducted as hazardous. [3]

Under the influence of these accidents, it is clear that the decade of the 1960s laid the basic foundation for the modern framework for safety during high-consequence activities. The SL-1 accident raised awareness that the simple declaration of "human error" should not be the end of an incident investigation, but rather it should be the start of a deeper probing of the human and organizational aspects of the incident. The loss of the USS Thresher raised the awareness of the need for safety management systems that ensure that safety-related requirements have been adequately identified and properly implemented in high-consequence operations. Finally, the Apollo 1 fire raised the awareness that complacency represents a real danger, and that organizations conducting high-consequence operations must always be uneasy with any situation and vigilant at all times.

1.2. The formative decade, 1970-1979

The frequency and significance of major accidents increased significantly in the decade of the 1970s. It could be argued that society had become “less safe,” but it is more likely that the rapid growth in the use of highly technical and complex systems increased societal exposure to high-consequence activities. In other words, the number of opportunities for failure increased instead of the rate at which failure occurred.

On April 13, 1970, an explosion in an oxygen tank crippled the Apollo 13 command module while the spacecraft, with three astronauts onboard, was transiting from the earth to the moon. The physical cause of the accident was determined to be undetected damage to the oxygen tank that had occurred during initial testing of the tank years before. Improvised procedures during initial testing, used to circumvent a minor flaw, resulted in the failure of a part that was underrated for its intended function. When called upon to function inflight, the failed component generated an electrical spark, causing the tank to explode. With echoes to the Apollo 1 accident, there is a suggestion that complacency may have played a role in failing to recognize this design error: “the tank which failed, the design of which is criticized in this report, is one of a series which had thousands of hours of successful operation in space prior to Apollo 13.” [4]

However, it is not the accident that makes the Apollo 13 important to this paper, it is what happened after the accident. As the investigation report states, “the accident is judged to have been nearly catastrophic. Only outstanding performance on the part of the crew, Mission Control, and other members of the team which supported the operations successfully returned the crew to Earth.” [4] By all accounts the crew should not have survived this accident; there was no pre-planning or mechanism for rescuing the crew and there were no procedures for recovery from such an event. But with strong leadership, a high degree of technical competence, cautious improvisation, and dedicated teamwork in both the spacecraft and on the ground the crew safely returned to earth.

On March 3, 1974, Turkish Air flight 981 crashed near Paris, killing 346 people. An improperly serviced cargo door opened during ascent, and the rapid depressurization caused a section of the passenger deck floor to collapse and sever flight control cables. [5] About four months later a massive explosion at a chemical plant in Flixborough, England, decimated the plant and the local community, killing 26 people. Fortunately, this accident occurred on a Saturday afternoon, or the number of casualties would have been much higher. An improvised modification of a process line failed, causing a massive release of highly flammable vapors. [6] In both of these accidents errors occurring during maintenance combined with design weaknesses to cause catastrophic consequences. James Reason later refers to these accidents and notes that “maintenance errors … are not just isolated causes … they are themselves consequences of upstream organizational factors.” [7]

On March 27, 1977, two Boeing 747 aircraft, the largest commercial airliner in the world at the time, collided on a foggy runway at Los Rodeos Airport, Tenerife. The collision resulted in the death of 583 people. Besides the magnitude of the consequences, this accident is notable in that the causes of the accident are all human and organizational in nature; there were no significant technical failures implicated. [8]

The First Seminal Event in the history of HRO and nuclear safety culture occurred nearly at the end of the formative decade of the 1970s. On March 28, 1979, a stuck pilot-operated pressure relief valve at Unit 2 of the Three Mile Island Nuclear Generating Station in the United States led to a meltdown of roughly two-thirds of the reactor core. Most of the radioactive material was contained within the reactor vessel and containment structure, but a relatively small amount was released through inadvertent and intentional venting to the atmosphere. [9] Although there were no injuries or excessive radiation exposures, this event is considered to be the most serious nuclear reactor accident in the United States. The public outcry about the accident nearly led to the collapse of the American nuclear power industry.

Pressure relief valves often get stuck open; in fact the comparable valve had stuck open at another nuclear power plant only 18 months before. These plants were designed to accommodate such failures, and this event in isolation would not have led to a core meltdown. However, numerous organizational latent conditions, such as misaligned valves, ambiguous console indications, inadequate procedures, and difficulties with the interpretation of the available information resulted in a failure to properly recognize and respond to the stuck valve. In fact, those latent conditions served to compound the magnitude of the accident by leading the operators into taking actions that worked counter to the operators' intent. [9]

Besides the near-collapse of the nuclear industry in the United States, this event was a watershed for the U.S. Nuclear Regulatory Commission (NRC), the industry, and the academic and practical study of human error and human performance. The President's Commission charged with investigating the accident concluded that:

> *To prevent nuclear accidents as serious as Three Mile Island, fundamental changes will be necessary in the organization, procedures, and practices -- and above all -- in the attitudes of the Nuclear Regulatory Commission and, to the extent that the institutions we investigated are typical, of the nuclear industry.* This conclusion speaks of *necessary* fundamental changes. We do not claim that our proposed recommendations are sufficient to assure the safety of nuclear power. [9, emphasis in original.]

In addressing the findings of their investigation, the President's Commission went on to say

> [A]s the evidence accumulated, it became clear that the fundamental problems are people-related problems and not equipment problems.

> When we say that the basic problems are people-related, we do not mean to limit this term to shortcomings of individual human beings -- although those do exist. We mean more generally that our investigation has revealed problems with the "system" that manufactures, operates, and regulates nuclear power plants. There are structural problems in the various organizations, there are deficiencies in various processes, and there is a lack of communication among key individuals and groups.
>
> …The equipment was sufficiently good that, except for human failures, the major accident at Three Mile Island would have been a minor incident. But, wherever we looked, we found problems with the human beings who operate the plant, with the management that runs the key organization, and with the agency that is charged with assuring the safety of nuclear power plants.
>
> …We are tempted to say that while an enormous effort was expended to assure that safety-related equipment functioned as well as possible, and that there was backup equipment in depth, what the NRC and the industry have failed to recognize sufficiently is that the human beings who manage and operate the plants constitute an important safety system. [9]

1.3. The nurturing decade, 1980-1989

As with the previous decade, the frequency and magnitude of major accidents continued to increase significantly during the decade of the 1980s. As the awareness of how human and organizational performance began to spread outside of the nuclear and academic environments after Three Mile Island, we begin to see those similar concerns expressed in other industries.

Three major accidents in the first three years of the 1980s all graphically illustrated how organizational weaknesses embedded into a system during the design or construction processes can later manifest themselves in disastrous ways. On March 27, 1980, the offshore platform Alexander L. Kielland capsized during a storm in the North Sea, killing 123 workers. The platform was a hotel-like facility intended to provide a rest area for offshore workers coming off their shifts. Improper construction techniques coupled with inadequate quality controls had resulted in undetected weaknesses in one of the platform's legs, which failed catastrophically during the storm. In addition, inadequate emergency preparedness left the workers with insufficient means for abandonment of the platform. [10]

On July 17, 1981, elevated walkways at the Hyatt Regency Hotel in Kansas City collapsed during a dance, killing 111 participants. The loading on the walkways was within the design basis, but during construction the hangers for the walkways had been modified to simplify construction. The modifications were never analyzed to ensure that the design basis was still satisfied. [11]

On February 15, 1982, the offshore drilling rig Ocean Ranger capsized during a storm in the Atlantic Ocean, killing all 84 workers onboard. Design weaknesses left the room containing the electronic control console for the ballast system vulnerable to water intrusion during high seas, and the operators were not trained to understand and operate the system manually, even though a manual control system was installed. Once ballast was lost inadequate training and emergency preparedness left the workers without an effective means to abandon the platform and survive in the cold North Atlantic waters. Those that did abandon the rig did not survive until help could arrive. [12]

On the night of December 3, 1984, a massive chemical release from a pesticide plant spread through highly populated local areas of Bhopal, India. Many died from the acute exposure, others died from injuries and illnesses caused by the exposures. The number of casualties has never been accurately determined, but it has been estimated that between 3,800 and 16,000 people died from the accident. This accident is believed to have been a result of the accumulation of a large number plant deficiencies due to inadequate maintenance, insufficient staffing and training, and poor management. This accident generated a major emotional impact on the public and the chemical industry worldwide, and could have served as a seminal event. However, the investigation of the accident became embroiled in legal and political battles between the joint owners of the plant, the Indian government and an American chemical company, and a consensus view of what happened and why never emerged. As a result, the lessons learned from the event were limited and the accident's full impact as a driver for change is indeterminate. [13]

On January 28, 1986, the American space shuttle Challenger was destroyed in a deflagration over the Atlantic shortly after its launch from Cape Canaveral, Florida, killing all seven astronauts on board. The Presidential Commission's investigation determined that due to abnormally cold ambient temperatures over the previous night and up to the launch time, rubber O-rings used to seal joints in the casing of the solid booster rockets had lost flexibility. The inflexible O-rings failed to seal the joints and allowed hot gases to escape and impinge on the external fuel tank, causing it to fail. Although this accident had an immediate impact on America's space program, its most significant impact on the general safety of high-consequence activities was slower in coming. Eleven years after the accident, Diane Vaughan published her extensive study of the organizational framework and behavioral patterns that influenced the decision to launch on that day. In this study she defines the concept of the "normalization of deviance," an informal process by abnormalities and deviations in a system slowly become accepted as normal and expected. In effect, the process results in a slow, unrecognized erosion in the margin of safety from the level the system was designed for. When put into this conceptual framework, the lessons learned from the accident had a much larger impact that extended into all industries conducting high-consequence activities. [14]

The Second Seminal Event occurred three months after the loss of the Challenger. On April 26, 1986, Unit 4 of the Chernobyl Nuclear Power Plant in Ukraine underwent a severe power excursion during a residual power test, resulting in multiple steam and hydrogen explosions. The unit was completely destroyed, the entire reactor core was exposed to the ambient atmosphere, and it burned and released radioactive material into the atmosphere for several days. As a result of the explosions and the initial firefighting efforts, 31 people were killed. Radioactive contamination in the immediate area led to the evacuation of 135,000 people from within 30 km of the plant; contamination farther from the plant led to temporary restrictions on the distribution and sale of agricultural products in several European countries. [15]

The International Atomic Energy Agency (IAEA) investigations concluded that the accident was "the result of the concurrence of the following major factors: specific physical characteristics of the reactor; specific design features of the reactor control elements; and the fact that the reactor was brought to a state not specified by procedures or investigated by an independent safety body. Most importantly, the physical characteristics of the reactor made possible its unstable behaviour." [16]

The impacts from this accident were felt globally. Public concern over the safety of nuclear power nearly led to the global collapse of the nuclear power industry. Extensive safety evaluations were conducted of operating and planned nuclear power plants, but the unique design of the reactors used at Chernobyl limited the applicability of the lessons learned from the identified technical weaknesses in the plant's design and the reactor's physical characteristics.

However, the most significant and lasting impact of the accident came when the IAEA concluded that

> The root cause of the Chernobyl accident, it is concluded, is to be found in the so-called human element. The lessons learned from this imply three lines of action:
>
> 1. Training, with special emphasis on the need to acquire a good understanding of the reactor and its operation. and with the use of simulators giving a realistic representation of severe accident sequences;
> 2. Auditing, both internal and external to the utility, in particular to prevent complacency arising from routine operation;
> 3. A permanent awareness by all personnel of the potential safety implications of any deviation from the procedures.
>
> These lessons drawn from the Chernobyl accident are valuable for all reactor types.
>
> The vital conclusion drawn is the importance of placing complete authority and responsibility for the safety of the plant on a senior member of the operational staff of the plant. Formal procedures properly reviewed and approved must be supplemented by the creation and maintenance of a 'nuclear safety culture'. This is a reinforcement process which should be used in conjunction with the necessary disciplinary measures. [15]

The IAEA also expressed significant concern regarding the attitudes and actions of individuals at all levels within both the operating organization and the government's regulatory body. "The accident can be said to have flowed from deficient nuclear safety culture, not only at the Chernobyl plant, but throughout the Soviet design, operating and regulatory organizations for nuclear power that existed at the time. Nuclear safety culture … requires total dedication, which at nuclear power plants is primarily generated by the attitudes of managers of organizations involved in their development and operation. An assessment of the Chernobyl accident in this respect demonstrates that a deficit in nuclear safety culture was inherent not only to the stage of operation, but also and to no lesser extent to activities at other stages in the lifetime of nuclear power plants (including design, engineering, construction, manufacture and regulation)." [16]

In these passages the concept of nuclear safety culture was born. The IAEA went on to establish a definition of nuclear safety culture as "that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance. [17]

Unfortunately, the nurturing decade of the 1980s did not end with the Chernobyl accident. Between March of 1987 and July of 1988 three accidents occurred in the United Kingdom that also had significant influence on the development of nuclear safety culture, even though they were not nuclear accidents. On March 6, 1987, the auto and passenger ferry Herald of Free Enterprise capsized in the English Channel shortly after leaving a Belgium port, killing 193 people. A combination of organizational weaknesses led to the ship leaving port with her bow doors open and with ballast tanks filled improperly. As the ship gained speed, water began to enter through the open doors in large quantities and the ship capsized within 90 seconds. [18]

Eight months later, on November 18, 1987, fire broke out in the King's Cross St. Pancras Tube Station in London, killing 31 people. The investigation concluded that a discarded burning match had fallen into and ignited a pile of debris under a wooden escalator. The fire quickly spread due to excessive combustible loading and a previously unrecognized "trench effect" that fanned the flames. The investigation also concluded that the attitudes of were "lax" towards the possibility of fires in the facility, so that the significance of the hazard was underestimated by both the facility staff and the local fire brigade. [19]

Eight months after that the King's Cross fire, on July 6, 1988, the offshore oil platform Piper Alpha exploded and burned in the North Sea as a result of a major gas condensate leak. There were 167 workers killed. The platform was undergoing major maintenance and system upgrades at the time of the accident, but production operations continued at the same time. Investigators concluded that, due to the inadequate control and communication of the status of plant systems, operating staff had switched gas condensate flow to an out-of-service condensate pump line that had been opened for servicing, resulting in the massive gas leak. [20]

The nurturing also continued in the United States during the closing year of the 1980s. On July 19, 1989, the tail engine of a DC-10 passenger aircraft catastrophically failed while the aircraft was at cruise altitude. Debris from the failed engine entered the aircraft and severed the hydraulic lines from both the primary and the backup flight control systems, rendering the aircraft uncontrollable. Despite the fact that such an accident – the loss of all flight controls – was believed to be unrecoverable, the pilots managed to regain control of the aircraft with improvised techniques and they kept the craft airborne for 45 minutes in order to reach the nearest major airport. Although they lost control of the aircraft during the approach and crash landed on the runway, 185 of the 296 people onboard survived the accident due to the actions of the pilots. [21] As with Apollo 13, strong leadership, a high degree of technical competence, cautious improvisation, and dedicated teamwork in both the aircraft and on the ground greatly reduced the magnitude of the disaster.

The nurturing decade finally drew to a close on October 23, 1989, when massive explosions and fire rocked the Phillips' 66 Houston Chemical Complex in Texas, killing 23 people. During a routine maintenance activity being performed without taking the chemical reactor involved out of service, an isolation valve was inadvertently opened, releasing the entire contents of the reactor into the area. The released material was a highly flammable vapor that soon found its way to an ignition source, leading to the initial explosion. The investigation determined that the air hoses that operated the isolation valve had been incorrectly connected, resulting in the valve opening when commanded to close. The investigation also determined that "Phillips had not acted upon reports issued previously by the company's own safety personnel and outside consultants who pointed out unsafe conditions;" existing safe operating procedures were not required to be used for this particular maintenance activity; there were no permanent combustible gas detection and alarm systems near the reactors to provide warnings of leaks; ignition sources were located in the area without flammable gas testing; and the fire protection system was not adequately maintained. [22]

2. ORGANIZATIONAL CULTURE AND ACCIDENTS

So what do all of these accidents have in common, and why did those common observations coalesce into concrete concepts and frameworks for action?

First, there is the human element; errors in decisions, actions, communications, and or understandings were significant contributors to all of these accidents. This is not unusual, as most accidents involve human error. But in each of these accidents, the investigation usually revealed wide-spread significant human and organizational performance failures, such as:

— Multiple breakdowns in safety processes, barriers, and mitigation systems existed in various elements of organization prior to the accident;

- Significant differences between "work as imagined" and "work as performed" at multiple levels in organization;
- Multiple examples of the lack of awareness or acceptance of deviation by supervision;
- Patterns that demonstrated a recurring failure to recognize or analyze the safety significance of hazards, situations, decisions, or actions prior to accident; and
- Feedback and improvement processes designed to detect and/or correct process breakdowns were either nonexistent, ineffective, or ignored by managers.

Typically, the types of complex technical systems where these accidents occurred, whether they be nuclear reactors, chemical plants, commercial aviation, or offshore platforms, are designed and operated with multiple overlapping barriers and processes in place to ensure that one or a few isolated errors or component failures will not result in a major accident. However, what we observe in these accidents is that the responsible organizations have allowed serious breakdowns in those processes and barriers to accumulate without correction. One would like to believe that these were failures in recognizing the breakdown, but in many cases the breakdowns had been recognized but had either not been corrected or they had been accepted as the new norm.

Since these breakdowns tended to occur within different parts of the organization, this would suggest that there was a common-mode failure mechanism operating within the organization. In 1978 Barry A. Turner published his study of 84 accidents in Britain between January 1965 and December 1975. [23] The book was ahead of its time, and initially went unacknowledged, but it was the first to methodically explore the social and organizational aspects of major accidents. James Reason later credited Turner's book as one of the "intellectual origins" of the organizational model approach to safety management. [7] In the forward to the second edition of the book Diane Vaughan wrote that

> Both Turner and Pidgeon acknowledge that the causes of organizational-technical system failures are largely intractable, yet stress the importance of efforts at social control. As the millennium approaches, we witness the growth of global markets and economies with them, the proliferation of increasingly complex organizations and large-scale technical systems. The inherent failure potential scripted into the complex technical systems and complex organizations can only catapult, as cultures and international politics complicate organizational outcomes. [23]

Based on his studies, Turner recognized that before major accidents occurred there were preconditions in the organization that developed over a period of time that he called the incubation period. It is that same pattern that we are seeing in these accidents. Those human and organizational performance failures observed in the accidents discussed above are Turner's preconditions. Those performance failures did not occur instantaneously as the accident progressed, they accumulated without correction during an incubation period prior to the accident.

Both the development of these preconditions in an organization and the failure of the organization to recognize and/or correct those preconditions are due to the characteristics of the organization's culture. In other words, the organization's culture is the common-mode failure mechanism for organizational accidents.

Although there were some researchers such as Turner already looking at major accidents from an organizational perspective, the investigation into the Three Mile Island accident by the President's Commission served as a tipping point, inspiring or greatly increasing work in the areas of human factors engineering, human error, and human and organizational performance. For example

- The U. S. Nuclear Regulatory Commission initiated a self-investigation of its role in the accident, which led to a complete restructuring of the agency, its regulations, and its oversight processes;
- The nuclear power industry in the United States established the Institute of Nuclear Power Operations (INPO) in December 1979, as recommended by the President's Commission; and
- The NRC began major efforts to encourage and sponsor the academic and practical study of human error and human factors.

The Three Mile Island accident also inspired a large number of both academic and popular publications, with probably the most influential being Charles Perrow's Normal Accidents. [24] The concepts developed in this book, now referred to collectively as the Normal Accident Theory (NAT) have received a lot of attention over the years, and have inspired much research. One of the most widely recognized offshoots from the book is the research into the attributes of High Reliability Organizations (HRO). Later, in 1993 Scott Sagan published The Limits of Safety, [25] which compared and contrasted NAT to HRO with a series of case studies drawn from the management of nuclear weapons during the Cold War. Karlene Roberts described the relationship between Normal Accidents and the HRO work,

> In his well-known book, *Normal Accidents*, Charles Perrow concluded that in highly complex organizations in which processes are tightly coupled, catastrophic accidents are bound to happen. Two other sociologists, James Short and Lee Clarke, call for a focus on organizational and institutional

> contexts of risk because hazards and their attendant risks are conceptualized, identified, measured, and managed in these entities. … The realization that major errors, or the accretion of small errors into major errors, usually are not the results of the actions of any one individual was now too obvious to ignore.
>
> This set the stage in 1984 for a research group at the University of California at Berkeley to begin to study organizations in which errors can have catastrophic consequences. They focused initially on organizations that seemed to behave very reliably, which they called high reliability organizations (HROs). Another group at the University of Michigan began addressing similar issues. While these people represented different disciplines (psychology, political science, physics), they came together with an organizational perspective. These researchers took a different perspective than most of those who preceded them. They were initially concerned with understanding success in organizations in which errors can result in catastrophe." [26]

In addition to those researchers working on NAT and HRO, researchers who were already working in areas associated with human error, human factors, and organizational performance, such as James Reason, Jens Rassmussen, Eric Holnagel, Alan Swain, and others gained prominence as the topics of their research became the center of attention in the nuclear world.

While the Three Mile Island accident inspired work into human and organizational performance concerns, the concept of nuclear safety culture introduced after the Chernobyl accident brought forward concerns about organizational leadership, decision-making, priorities, and individual attitudes. Pierre Tanguy, one of the members of the International Nuclear Safety Advisory Group during the initial review of the Chernobyl accident, talked about the influence of the SL-1 accident in a 1988 paper by quoting The Technology of Nuclear Reactor Safety (1964):

> Most accidents involve design errors, instrumentation errors, and operator or supervisors errors. The SL1 accident is an object lesson on all of these. There has been much discussion of this accident, its causes, and its lessons, but little attention has been paid to the human aspects of its causes. There is a tendency to look only at what happened, and to point out deficiencies in the system without understanding why they happen; why certain decisions were made as they were. Post-accident reviews should consider the situation and the pressures on personnel which existed before the accident… [27]

As was noted earlier after the Three Mile Island accident, some of these events raised such serious concerns that they motivated changes within their presiding regulatory systems. For example

— The 1987 King's Cross St. Pancras accident led to new fire precautions regulations in the United Kingdom;
— The 1988 Piper Alpha accident led to the establishment of a completely new regulatory system within the United Kingdom, based on the development of a safety case – a detailed safety analysis of the activity – and the implementation of the controls identified in the safety case by the operator, along with regulatory and oversight bodies responsible for overseeing and enforcing the implementation of the safety case;
— The 1989 explosion at the Phillips' 66 Houston Chemical Complex led to the establishment of the Process Safety Management regulations in the United States.

3. CONCLUSION

First, recognize that organizations and people profit from taking risks. This is normal and should be anticipated; it is, after all, how business proceeds and technical progress is made. But the history of major accidents described in this report reminds us that there are basic questions that we should always be asking,

— Do we understand the magnitude and nature of the risk?
— Are we allocating our resources based on our safety priorities?
— Are we monitoring the absolute values and relative trends between safety and mission resources?
— Do our relative trends reflect where our safety priorities our lay?
— Are our safety and mission resources changing consistently?

As Sidney Dekker noted, "real progress on safety can be made by understanding how people create safety, and understanding how the creation of safety can break down in resource-limited systems that pursue multiple competing goals." [28]

Second, recognize that organizational accidents are not rare or extraordinary events; they occur all the time. The difference between most workplace accidents and an industrial disaster is not the magnitude of the failures, it is the magnitude of the consequences that result from those errors. Given that an organizational accident can entail any number and variation of failures in both control and mitigation systems, each accident has a spectrum of possible consequences depending on the exact circumstances at the time the initiating event occurs. What this means is that essentially every workplace accident discloses something about the vulnerabilities that exist in the organization. We should not wait until the magnitude of the consequences are too great to ignore, we should understand that all accidents are organizational learning opportunities.

Third and finally, we must accept that there will be times when our efforts to maintain the highest levels of organizational and system safety will fail us; at those times we will need to rely solely on the individuals we chose to conduct those activities to respond to the situation as it unfolds. We must always ensure that those individuals are strong leaders, possess a high degree of technical competence and experience, are capable of cautious improvisation, and are supported by equally competent and dedicated team members. These leaders and teams do not come about by happenstance; they must be carefully selected and properly prepared.

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PATIENT SAFETY, PRESENT AND FUTURE

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Abstract

Healthcare is undergoing an unprecedented trust and value crisis. It is grasping for quick and easy solutions and trends to oversimplify system safety concepts. Patients still experience needless harm and often struggle to have their voices heard, processes are not as efficient as they could be, and costs continue to rise at alarming rates while quality issues remain. We tend to think about patient safety in a linear dimension that is only associated with the progressive reduction in the number of errors and accidents, with the simple notion that more is always better. We consider figures in isolation from the underlying context, prerequisites of risk models and the affordances of clinical domains. There is no ultimate reference model for patient safety, but many models that can be adapted to fit the clinical requirements and constraints. It is therefore not necessarily a bad result to observe a lower safety figure in a medical domain compared to the figures obtained in non-medical ultra safe models. The poor safety figures may represent the best safety optimization while coping with the special, local healthcare requirements such as a high frequency of unplanned and non-standardized challenges. The paper distinguishes three classes of safety models that fit different field demands: the resilient (adaptive), the high reliability (HRO), and the ultra safe models. The paper benchmarks the traits of each model while highlighting the specific needs for optimization. Since no model is ideal, there are numerous general lessons going well beyond the specifics of healthcare and addressing other industries, namely nuclear industry.

1. INTRODUCTION

Complex professional human activities are subject to a large range of frequent failures and catastrophes [1]. Some vocations experience an accident in every 10 trials (i.e., professional mountaineers in Himalaya [2] while other vocations are almost a million times safer—0.8 accidents per million departures in Civil Aviation. We call the later ultra-safe domains [3]. The healthcare safety figures are relatively modest in comparison, where we expose one in 1000 hospitalized patients, on average, to significant and preventable morbidity and mortality [4].

These suboptimal outcomes frustrate healthcare leaders and regulators and underscore the two health reform drivers needed to improve healthcare. Firstly, the safety performance of most industries, and this is equally true for healthcare, have not improved much over the past decade [5-8]. Secondly, the dominant approach to improvement is to try harder to understand why safety champions (i.e., lead hospitals) have succeeded, and import ideas to help weaker performers. The theory is that the safest hospitals have the best outcomes and thus have necessarily implemented the better safety models.

Ten years ago, we listed five main barriers for healthcare to become an ultra-safe system [1] (a) accepting limits on performance and regulations; (b) limiting physician autonomy; (c) abandoning craftsmen attitudes and accepting equivalent actor status; (d) avoiding ego-centered solutions, protocols and “safety umbrellas”(bureaucracy of protocols); and, I increasing the visibility of risk to system users.

In this paper, that touched a raw nerve and has been highly cited, we argued that there is a need to balance the advantage of becoming ultra-safe with the inherent sacrifices of resilience and adaptive capacity to the unexpected. We must never forget that the first challenge of medicine is to give hope for wellbeing and longevity. Mirroring ultra-safe systems may represent a double-edged sword against reliable and safe outcomes. Firstly, we argue from a conceptual bias, that since the ultra-safe model introduces the idea of a unique model of safety, a sort of ultimate model for all industries and services. However, that is only partially true as there are at least two other authentic models of safety with their respective advantages and disadvantages, the resiliency (RES) and the high reliability organization (HRO) models. Secondly, from a theoretical field bias, we considered the safety model in isolation of the productivity and organizational demands of healthcare. Hollnagel reminds us in the ETTO principle that people make trade-offs (i.e. sacrifices) by adjusting their normal work to match the current conditions between efficiency and thoroughness demands under conditions of limited resources and uncertainty. [9]

2. BENCHMARKING THE SAFETY

2.1. The adaptive (resilient) model versus the ultra safe model

Two of the world’s most acknowledged dangerous professions, combat fighter piloting and open sea fishing enable a discussion about the models of safety in unstable environments (10,11). Modern combat fighter aircraft are required to fly under extremely unstable conditions (i.e., low altitude, high speed and gravity forces, nighttime, inclement weather, etc.). Combat flight under extreme human factor circumstances is a valuable example to appreciate the model of safety developed for these extreme conditions. This work is supported by an authentic safety model totally different from civil aviation even though many of the combat pilots fly in commercial aviation after they leave the military. Pilots develop a sophisticated mental model and a situational awareness in order to anticipate problems and actively avoid or minimize these problems [9]. The combat flight safety model is based on five tenets: (a) deference to expertise; (b) long training, immersive learning and simulation programs to cope with surprises including special training to anticipate (pre-planning), adaptation, and re-planning; (c) metacognitive training to estimate whether their expertise can overcome a given challenge or not;

(d) permanent scepticism of one's ability to estimate and grasp errors and recovery; and, I a fighting social culture that socializes pilots to face high risks, and potential death, as an inherent and acceptable component of their job.

Commercial deep-sea fishing, the world's most dangerous profession, sheds light on another aspect of this class of high-risk activities [10]. In the year 2000, there were 100 fatalities a year per 100,000 sailors [11]. This results are in comparison to 15 fatalities per 100,000 in the building trade industry (considered to be one of the most dangerous high-risk sectors) and 3.2 fatalities per 100,000 full-time equivalent workers in other fields in 2011. Studies demonstrate that from the time the sea boats leave the 55arbour, the fishermen are unwilling to cancel their trip and return to 55arbour even in the most extreme weather conditions, and regardless of whether or not the catch was good [12-14]. The sea captains and sailors, not being suicidal, however, use multiple expert strategies and heuristics to reduce the risk without having to give up their fishing activity. The model that fighter pilots use is remarkably similar despite the very different circumstances, cultures and technologies.

The sea fisherman model of safety is an example of the resilient model, which is defined as the ability of a system to adapt and sustain key operations in the face of expected or unexpected challenges or opportunities [15]. These professionals are used to working in very small teams of less than ten personnel, sometimes even by themselves, with a craftsmen's spirit. They challenge and compete with colleagues and adversaries with the goal of becoming the winner. They take the risk, represented metaphorically, by climbing mountainous cliffs in very adverse conditions. Climbing incompletely planned or even unknown mountain routes is not only frequent, it is the essence of their profession. Because they climb difficult cliffs, they develop incredible meta-cognitive abilities, including the constant surveillance of, and reflection on, their own cognition and errors. This heightened situation awareness enables them to prepare for the challenging and risky scenarios when serving in the open sea. For example, Amalberti and Deblon [10] identified the exceptional skills found in fighter pilots, who constantly orient the situation in which they are about to place themselves as a function of the perception of, and reflection on, their own abilities to manage these situations (i.e., status of the context, previous results in comparable situations, flight fatigue, etc.). Oncology is a good example of ultra-resilient model in medicine, which shares many of these characteristics towards risk and operations. (see Box 1)

Box 1: Oncology strives for new challenges, searching for extra gains for the patient with cancer. These new avenues are paved at a very high rate of adverse events, although the benefits are weighted considered higher than harm because of the special status of oncology as a last-resort. The model works because oncologists take risks on the basis of a considerable cumulative personal and collective experience and also because all participants *including the patients* share the willingness to take extra risks. What makes the system typically ultra-resilient, in addition to the great autonomy of oncologists, the high level of novelty, and the inherent risk-taking of the specialty, is also the way oncologists report, share and continuously learn from the past: they first give way to past successes and not so far to past failures. This learning culture is predicated on publicizing improbable successes rather than reporting adverse events. Successes guide the future. Conversely, failures are expected and relatively disregarded as dead-ends. Nevertheless, there are considerable differences in safety among oncology wards. Safer wards, or patients achieving better outcomes, are characterized by better expertise, namely better strategies for implementing novel solutions as well as applying more effectively lessons from dealing with complications. These strategies include implementing a clinical microsystem based approach (ref), relevance of patient enrollment, special surveillance, good sense of what is feasible giving the local context and what is not (metacognition), quality on-line criteria to use for adaptation, and active participation and education of patients and their carers.

The 'ultra-safe' civil aviation model, in comparison to these domains, enables us to compare a considerably different model of safety. The ultra-safe model is based on two points; firstly, the ability of the organization to protect workers from exposure to dangerous occupational situations [16]. Civil aviation has long given up on training pilots when pilots are at risk in heroic measures to face dangerous "cliffs". Detailed planned and rehearsed responses and activities are at the core of safe aviation. Civil aviation will ground passengers and planes at the departure airport when the destination airport is under stormy conditions, crew are fatigued, or divert the flight, hence the reduced need to train pilots to land in stormy conditions. Secondly, civil aviation is a remarkable example of the ability of the organization to develop and enforce a full set of worldwide accepted and standardized regulations and protocols. The ability to impose a full supervisory control of workers (i.e., Air Traffic Control, flight recorders, fines, etc.) and to enforce aviation employees to comply with these protocols have enabled aviation to become ultra-safe. Aviation workers have clear and separate complementary roles and strict crew protocols are enforced. The two models have obvious differences in their safety and control characteristics and implications for healthcare. Laboratory medicine is a good example of an ultra-safe system in medicine, **see Box 2**

Box 2: Laboratory examinations are performed and results delivered that follow a strict set of procedures, with no alternative, except for a limited set of degraded solutions fitting a few specific contexts (e.g., equipment failure). But even these few degraded solutions are totally anticipated, with no improvisation. The value of individual expertise (in adapting to adverse conditions) is considered less than the value of standardization and conforming to the protocol. When the procedure fails to work according to the quality protocol, or the values of the result remain doubtful, the results will never be transmitted to the ward whatever the real need and the supplications of this ward. The inability to do so will be considered a sign of good quality. The ward will patiently wait for all required conditions by the lab to redo the exam before releasing the results (this is similar to planes being grounded for hours, waiting for safe flying conditions before being allowed to take off). The art of Laboratory medicine is precisely to develop super-reliable procedures for normal and abnormal conditions, be capable of identifying any non-quality conditions, thus enabling high reliability. Conversely, on general med-surgery wards one must accept the wait on a certain test result, and accept that this high reliability scheme may restrain the availability of certain lab exams on nights and weekend. Nevertheless, there are significant differences within the various labs. Some work in superb and comfortable isolation, with little consideration for the wards and their difficult context of work and emergency, thus generating adverse events by absence of solidarity, whereas others invest in their organizations to deliver results in a timely manner. This type of organization and supervision may typically be taught to improve the global safety and quality of poor performing labs.

There are always three generic plans to face risks irrespective of the domain, medical or otherwise. Plan A consists of waiting for best conditions. For example, delaying a hip surgery to optimize patient readiness given co-morbidities, such as stabilizing congestive heart failure or unstable diabetes. Plan B consists of doing the job, ideally complying with recommended evidence (i.e., evidence based medicine protocols) and organizational benchmarks (i.e., staffing, technical equipment, etc.). Plan C consists of delivering care although all ideal conditions are not met (i.e., staff missing, equipment missing, competence missing, night and weekend conditions, small provincial unit, etc.).

The accreditation scheme used to speak about Plans A and B. This works for scoping the conditions of ultra-safe systems like Civil Aviation or laboratory medicine, but the reality of fishing industry, air combat, and the rest of healthcare is that these activities are predominantly concerned with plan C conditions. The challenge with plan C's is that the solutions that would make these practices safe while accepting their reality do not consist of developing procedures (if they did, one would change to a plan B approach). Instead the solutions are ad hoc and cannot address all the situations that emerge during the work demands and where the economic rationale often demands that it shift to plan C conditions (ref). Put it differently, the ideal vision (plan A and Plan B) hides the full reality of plan C's as if applying plan C is an error, and the only solution for enhancing safety should consist in suppressing plan C. A naïve risk strategy may therefore consider that we must reduce the number of plan C's. We can in some occasions do this, but we will never succeed in suppressing all plan C's because they are irrevocably associated with the immense benefits of round-the-clock healthcare readiness and coverage. Recent data, for example, suggest that elective surgical procedures are 82% more dangerous on weekends than when done on Monday [17].

Provided we accept that this conclusion makes sense, we must accept that the safety model of healthcare cannot be the ultra-safe model (which suppresses plan C). We need another model for improving safety for plan C without suppressing them. The two models have obvious differences in their safety and control characteristics.

2.2. The intermediate model: the High Reliability Organization (HRO)

The HRO model (High Reliability Organizations) [18-19] applies the same idea of resilience, since it also promotes adaptation, but this kind of adaptation is more local and controlled. It involves human activities which are clearly better organized, with a tendency to seek out daring exploits (which is more characteristic of the pure resilient model). The HRO model is in fact relatively risk-averse to individual exploits that are not controlled by the group. HROs typically apply to professions in which risk management depends on a daily and continuous affair, even if the aim is still to keep risk under control and avoid unnecessary exposure. This works well for firefighters, oil exploration, merchant navy and naval armed forces, and for professionals in the operating theatre but rarely works for other healthcare domains [20].

HROs rely on the team leader and the professional group, which incorporates several different roles and types of expertise in order to maintain a constant perspective on progress made towards the goal, while avoiding the pitfalls of only a local focus. All members of the group play a part in detecting abnormalities in a contextual setting (sense making), bringing them to the attention of the group, adapting the procedure to these changes in the context (ref grant and barach). This includes deviations from procedures when necessary (but only when this makes sense within the group and is communicated to everyone). [19] All members of the group show respect and solidarity in terms of this safety objective. Combating adversity is an integral part of the HRO approach but the high level of collective regulation (not necessarily only by the leader) imposes considerable limitations on isolated individual violations and promotes prudent collective decision-making.

Workers in HRO's are trained to develop mental pictures or cognitive maps, which are information-seeking structures within a perceptual-cognition cycle of exploration, constantly sampling and modifying as they go along [21]. Mental pictures guide an awareness to actively search for information and what may be considered important. Elective surgery in the operating theatre is a good example of an HRO model in medicine (see box 3).

Box 3: The operating theatres are scheduled for the entire week henceforth for all professionals, patients, and operating rooms. This does not accurately consider the frequent schedule changes. Significant changes occur every day, because of unanticipated structural reasons (i.e., technical failures, absenteeism), unanticipated functional reasons (physician/patients-associated surprises resulting in longer surgery, peri-operative complications, etc.). The art of adapting to these surprises is a core value for safety in this setting. All actors are required to check the situation regularly, understand and appreciate the changes, ask for coordination, and adapt accordingly. HRO principles may improve the safety of perioperative performance by a significant amount.

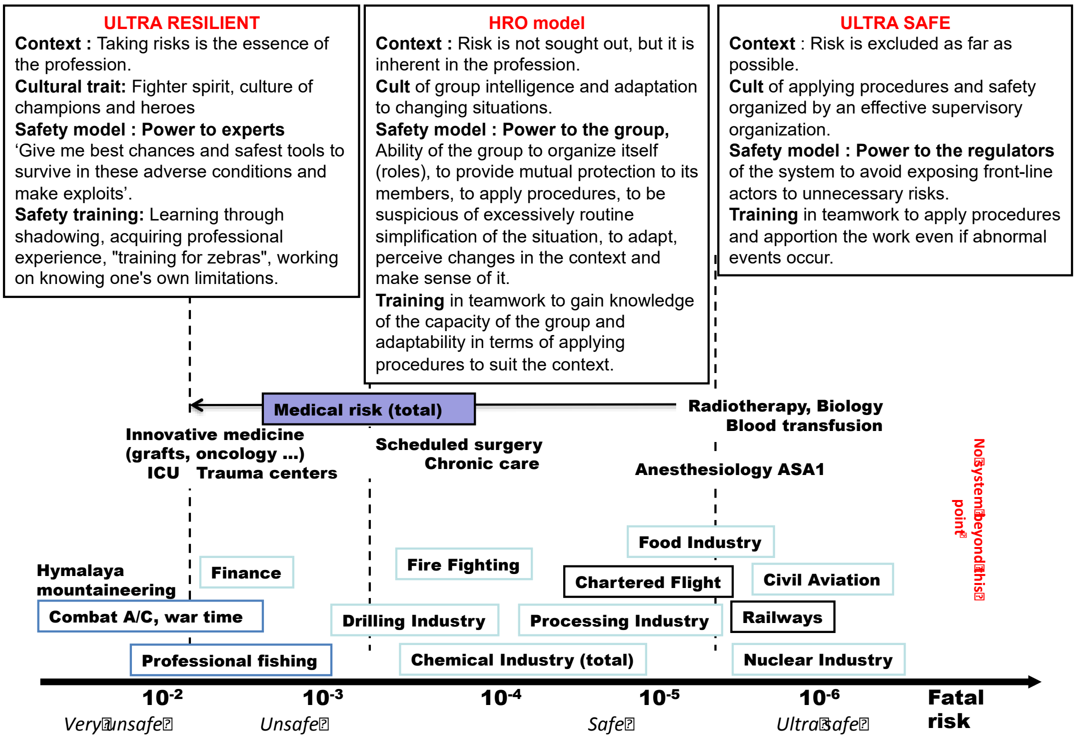

FIG.1. Three contrasted safety models

2.3. Variation in safety systems between best and worst performers

The three safety models predict a range of outcomes that vary by a factor of 4 to 10 among the best and worst performers for each category of work activity. The variation for ultra resilient high-risk activities follows this order of magnitude. For example, the risk incurred by deep-sea fishermen varies by a factor 4 to 6 between the best companies and the worst companies, depending if the figures are limited to shipwrecks or also include the occupational accidents at work [12, 22].

Surgery in the operating theatre has reported a variation in patient outcomes with a factor 4 to 10 fold range of difference in outcomes over the past 4 decades

[23, 24]. For example, the European Surgical Outcomes Study [25], an international 2012 study designed to assess outcomes after non-cardiac surgery in Europe, demonstrated important differences of in-hospital mortality between countries ranging, after adjustment for confounding variables, from 2% for Finland to 17.9% for Poland. For ultra safe activities, the largest safety difference regarding accident rates in civil aviation range from 0.63 crashes per one million departures in Western countries, to a rate of 7.41 crashes in African countries, a range of 10 fold variance [24]. Finally, the risk of a fatality from severe accidents (defined as more than five fatalities) in electricity plants per one million MWe, operating for one year between 1969-2000, is 157 in OECD countries, versus 597 accidents in non OECD countries. This represents a factor of 4 between the best and the worst performers [26].

There are two leading strategies to make a system safer. Either we use market leaders (champions) within the same category, trying to understand what makes the differences between poor and good performers. As shown above, the range of expected improvement may span a factor of 1 to 10 depending of where you start. Or we change the category, which may result in potential improvement by an impressive factor. First, however, we first need to change the working conditions (human factors), the environments of care imposed by the activity. If you cannot change these conditions, safety improvements will likely be more modest and consistent with local improvement being the most appropriate model rather than betting on a 'potentially better performing model'.

2.4. Consequences for healthcare safety and reliability

Healthcare tends to fall into two traps when trying to improve its outcomes. This is mostly likely due to a lack of fundamental systems and safety science training, and a lack of effective team collaboration in healthcare compared to other reliable industries [27-30]. Firstly, we could develop a unique quality and safety scheme based on evidence-based medicine principles (including both technical and organization) that fits 50 to 70% of patients, especially in front line specialties (i.e., emergency, ICU, Surgery, Oncology, etc.). In the remaining cases (30 to 50%) the work is done under degraded safety conditions with understaffing, lack of proper supervision especially at nights or weekends, competence missing (no senior doctors for example), and high levels of demand that overwhelm available resources. Although it is desirable to suppress these conditions as much as possible, we need to acknowledge that such conditions are largely inherent in the medical field, and will not change in the near future. The challenge is we have no alternative formalized model to guide professionals working in these conditions inviting them to local improvisation and rule breaking.

The recommended safety solutions are often incompatible with the way work is done, the guidelines remain for demonstration (certification), and little actual progress or change in workflow occurs [31]. Paradoxically, a selection of the best safety model characteristics that fit the constraints of healthcare (e.g. resilient model) would probably result in better optimization of safety, instead of dreaming about other models (not fitting the constraints).

The lessons for healthcare are clear. The imposition of a safety model does not change the task requirements, but changes in the task requirements may justify adopting a different safety model. If we do not change the constraints, it is more reasonable to select the most appropriate safety model for those conditions, and use the proper dimensions to optimize the outcomes, instead of pleading for another safety model. A different model may be intrinsically more effective, but we don't acknowledge that is inoperative in this context. Hence, the discussion comes down to what is politically feasible to change in healthcare and what is not. The answer is probably context dependent and will vary by discipline, organization and jurisdiction, respectively.

3. CONCLUSION

It is still unclear if a linear approach to safety in healthcare which forces all users to adopt the apparent best performing model is the best choice while risking wholesale disengagement by clinicians. Since this 'ultimate model' does not necessarily answer the demands of each clinical terrain. Transitioning from one model to another is not magical nor seamless and requires significant resources, headroom, and reflective learning. Each model is self contained, providing its own logic and satisfaction, and once the transition is completed, the properties of the previous model are gracefully degraded, and may even be lost. This is the case for the nuclear industry that has today very limited capacities (although none) to adopt a HRO style and even more a resilient style when needed by the unexpected context.

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SAFETY CULTURE: A REQUIREMENT FOR NEW BUSINESS MODELS

Lessons learned from other High Risk Industries

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Abstract

Technical development and changes in global markets affects all high risk industries creating opportunities as well as risks related to the achievement of safety and business goals. Changes in legal and regulatory frameworks as well as in market demands requires major changes. Several high risk industries are facing a situation where they have to develop new business models. Within the transportation domain, e.g. aviation and railways there is a growing concern related to how the new business models may affect safety issues. New business models in aviation and railways include extensive use of outsourcing and subcontractors in order to reduce costs resulting in for example negative changes in working conditions, e .g. work hours, employment conditions and high turnover rates. Some negative effects of the new business models have already been observed within the transportation domain such as degraded safety culture and higher mental workload. There are examples where a business model with several low-cost subcontractors can turn out to be much more expensive due to the need for managing risks on numerous interfaces. Other negative effects are social dumping by external contractors and loss of competence if procurement requirements are not taking quality and safety issues into account. The paper will present some lessons learned within the transportation domain which can be useful for the nuclear industry in facing the major challenges ahead.Assuring safety is a fundamental requirement for obtaining a license to operate a business in nuclear power, aviation and railways. Thus, safety culture is an essential requirement for a successful business and must be part of any new business model in high risk industries. In the future safety culture, management commitment to safety and leadership skills in creating safety culture will be essential. The paper will discuss how companies and public utilities are to achieve this and how the regulators are to assess this where learning across industries is a key success factor.

Keywords: safety culture, HTO, new business models, change management, working conditions

1. INTRODUCTION

Global competition and changes in legal and regulatory requirements demand extensive changes

Global markets and technical development affects all industries creating opportunities as well as risks related to the achievement of safety and business goals. Also, changes in legal and regulatory frameworks as well as market demands create a need for major changes in business models.

Therefore, high risk industries are facing a situation where they have to develop new business models. Within the transportation domain, e.g. in aviation and railways there is a growing concern how the new business models may affect safety issues since the new business models include extensive use of outsourcing and subcontractors.

The energy sector is also facing pressure to make rapid changes in business models but also in production facilities in the transition to renewable energy production. The nuclear industry is facing new legal and regulatory challenges. New reactor designs are available. The nuclear industry also has to on a large scale manage the life cycle state of phase out and decommissioning of nuclear facilities.

The new business models require changes in business strategies, management systems, work processes, employment models and working conditions. In order to ensure safety and safety culture in high risk industries new ways of working have to be developed both for companies and for regulators. Examples of such work practices from the aviation sector are regulatory requirements on cooperative oversight and risk based oversight. For example it has been suggested by the European Aviation Safety Agency (EASA) that the focus of aviation operators and regulators should be on management systems including new forms of employment, safety culture and the governance structure of the company, e.g. subcontracting and outsourcing.

Features of the new business models include using models from the private market based on markets that were previously heavily regulated or monopolistic. High risk industries rely on regulations and procedures in order to ensure safety and performance. Safety is an important part of the product delivered to the clients. Therefore features and effects of the new business models presents major challenges to safety management and safety culture in high risk industries.

The transportation sector has faced major changes in business models the last decade due to changes in regulations and market deregulations in Europe.

1.1. Challenges and changes in the energy sector

The energy industry faces major challenges. Major investments will be necessary to meet rising energy consumption as well as more stringent regulations. At the same time the utilities face pressure from customers, public opinion and legislators with respect to both climate and price issues. Deregulation and liberalisation has been ongoing since the electricity and gas markets were opened to competition across EU in 2007. The European market and its consumers demand lower energy prices at the same time as there is a need for funding major long term investment in new production facilities.

In addition, the decisions in Germany and Japan to shut down most of the nuclear reactors following the Fukushima Daiichi accident will reduce energy supply and production capacity. Reliable energy supply has to be maintained in a transition phase to renewable energy even though the electricity consumption is rising and many of the existing power plants have to be replaced.

Safety and reliability has always been an important prerequisite and not to mention a challenge for the nuclear sector and now economic competitiveness and financing, public perception and spent fuel and waste management including disposal are other major challenges.

Until recently nuclear energy has benefited from the initial investments being paid off and from a situation where license extensions, safety upgrades and power upgrades have been economically favourable. However, recent increased supply of cheaper energy prices and lower production costs from other sources have now had a negative effect on the energy economy creating stagnation in demand and prices on several markets. Nuclear powers high upfront capital costs and long lead times for planning, licensing and construction present challenges to financing and return on investments. Global negotiations on climate change and current policies in several countries promote renewable energy and provide subsidies for renewable production. Public acceptance has been challenged by major accidents.

The nuclear industry faces challenges in all of the above areas and strives to find new business models in a situation with rapid changes in several areas. The nuclear industry has to develop its capabilities in coping with new demands from stakeholders and the market as well as accelerating changes.

The transportation domain has already experienced and confronted some of these challenges. The paper will present some of the problems identified in the transportation domain, the lessons learned as well as highlight the learning potential for the nuclear sector using examples from the European market.

1.2. Changes in the aviation and railway sectors

The aviation sector and railway sectors have seen major changes and challenges related to deregulation of the market. In 1978 the US airline market was deregulated and subsequently requiring changes in business models. The airlines in Europe were deregulated in 1987 and the railway sector in Europe was deregulated around 2010.

In 2010 the European market on air traffic control (ATC) services was deregulated.

Thus, the European transport sector has experienced a high rate of change for the past 5-10 years affecting several high risk transportation domains.

Using the European air traffic control (ATC) as an example and in particular Scandinavia, some examples of the major changes in market demands and technical development introduced in the last decade are presented below.

In 2004 the common European airspace and open skies concept was launched in an EU directive. In 2006 a new, advanced technical platform for ATC increasing the automation level resulting in major changes in work processes, work situation and staffing for air traffic controllers was launched in some European countries such as Sweden and Denmark. Furthermore, in 2009 a common airspace for Sweden and Denmark was created. In 2010 the European market was opened to competition on ATC services and in Sweden the providers of ATC services and airport services were separated into different companies. The following year in 2011 there was competition on the national Swedish market providing for all airports to procure their ATC services from suppliers of their choice. The same year EASA introduced common targets for reducing costs on ATC services in Europe. In 2014 there was a reregulation of major, state owned airports in Sweden.

In summary, in five years the air traffic control (ATC) services in Sweden has gone from a regulated market to a completely deregulated market and back to a partly regulated market.

The example presented above illustrates the rapid changes in regulation and market conditions using ATC services as an example. Other safety critical industries are being exposed to the same changes. This will of course present major challenges to business models and safety culture in transportation and other industries where safe delivery of services is the major customer value.

1.3. New business models changes the HTO system and challenges safety culture

New and rapidly changing market demands as presented above will require changes in the business models of several high risk industries. The changes will among other things affect managerial practices and working condition.

By applying a systemic view on safety and production the effects on the Human, Organizational and Technical systems (HTO) can be identified, Fig. 1.

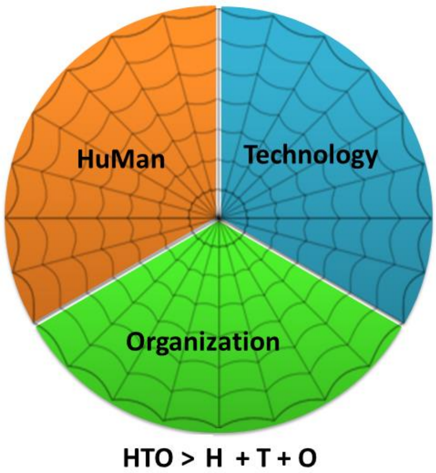

FIG. 1. Illustration of the systemic safety view and the interaction between Humans, Technologies and Organizations.

Safety culture is affected by changes in external requirements and demands. Changes in business models affect management values and strategies and also the social processes within organizations, Fig. 2.

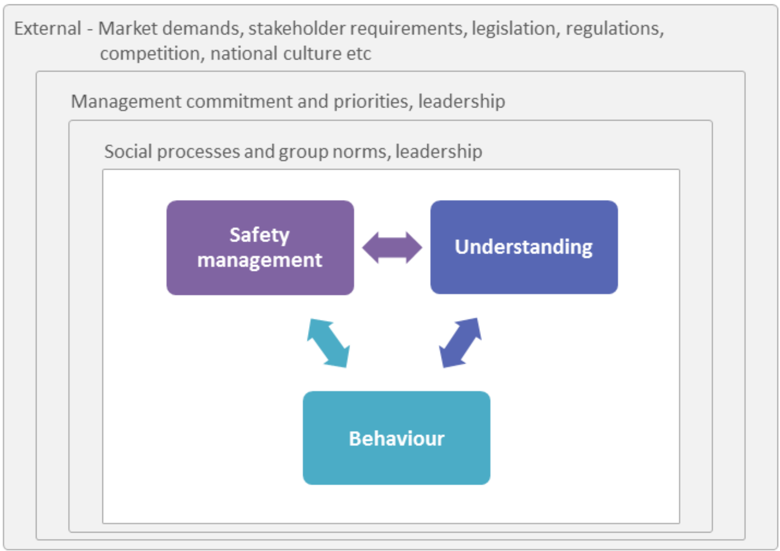

FIG. 2. Safety culture and the relation to external demands, management commitment and social processes.

In the next sections observations of the effects of new business models on safety culture and different parts of the HTO system will be presented.

2. CHARACTERISTICS OF A GOOD SAFETY CULTURE

Research on safety culture has identified a number of characteristics of a good safety culture (e.g. IAEA 1991, 2002, Flin et al., 2000; Guldenmund, 2000; Wiegmann et al., 2004; Reason, 1997, 1998 ;Reiman & Odewald, 2009, Watson, 2013). Most of the characteristics are interrelated. Some of the important characteristics are presented below and discussed in the results section.

2.1. Safety as a fundamental value and priority

Senior management must have safety as a basic value and as a fundamental part of the business model. The importance of safety must be clear to all staff members through for example safety policies, rules and procedures.

2.2. Management commitment and leadership skills

Management must be committed to safety and make this commitment visible and transparent by providing priorities and resources for safety work and communicate the importance of safety work continuously. Leaders´ communication downwards is one of the most important management practices for workplace safety (e.g. Mearns, 2003; Mattson, 2015). This means that leaders´ communication by expressing concern for the safety of individual employee and process safety are vital in achieving workplace safety and process safety. To use storytelling to develop safety culture is an important leadership skill where the leader explains past, present and future performance in terms of coherent stories (e.g. Packer, 2016) in order to shape people´s understanding and commitment to safety.

Also management must adopt a systemic safety perspective where all members of the staff are encouraged to view safety related issues as part of a larger organizational context. This means that managers and staff members can identify their own involvement and accountability in safety issues.

2.3. Trust and just culture

Mutual trust between managers and staff must exist along with a just culture is a necessary condition for proving opportunities for learning and will also counteract complacency. A just culture requires mutual trust, a sense of fairness and justice, shared values, well developed communication and reporting systems as well as work satisfaction and motivation (e.g. Cox et al., 2006).

2.4. Learning

Learning means creating fora and systems to promote learning. This means for example reporting occurrences but also to share best practices in order to improve work processes. Also, flexibility and adaptation is necessary to cope with continuous and frequent changes in technology and in the business environment. Trust and just culture is fundamental for learning.

Examples of systems for learning are processes to identify, analyse, correct and follow up on measures taken. Systematic processes for learning means implementing processes where the organization is able to learn from both own negative and positive occurrences within their own organization as well as to learn from other companies/partners.

2.5. Accountability

This means clarification of accountabilities for safety for managers and staff where all staff has a clear view on their own accountabilities. All staff members must understand their involvement in safety work and the lines of accountability must be clear.

New business models include subcontracting and procurement where accountability and interfaces between different companies must be managed.

2.6. Communication

Structures and means for communication must exist within the organization. This means both downward communication as well as upward communication. The upward communication relates to communication from subordinates to leaders. The communication is a means of providing feedback information to superiors related to for example improvement suggestions, and work- or safety-related problems. The upward communication is important for learning.

Also, vertical communication is important for learning. Examples are exchange of work practices and occurrence report. The organization must ensure arenas and means to provide communication and information exchange in order to promote learning.

2.7. Work situation, working conditions, work processes, tools and equipment

Adequate working conditions and work environment including adequate resources and work tools are essential for ensuring safety and thus a way of communicating safety culture. This means for example assuring an adequate balance between work demands and available resources. Control of work processes and work situation is also important. This includes for example scheduling and hours of work, staff with the right qualifications and adequate numbers. It also involves adequate tools and equipment to support the work tasks.

2.8. Safety culture and management of change

New market demands and new business models means changes. Safety culture is essential in order to uphold fundamental safety values in times of change. High risk industries are vulnerable in situations of financial difficulties when management focus often shifts from safety and quality to cost reductions. There are numerous examples where members of an organization perceive a shift in basic values from safety and quality to cost reductions. Research results show that companies with financial problems will have a lower safety performance (e.g. Bier et al. 2001).

It has been observed that safety critical organizations are more resistant to change than other businesses (e.g. Lofquist, 2011).

Also, that rapid changes in operational and organizational priorities often lead to reduced safety margins (e.g. Paries, 1995 and Amalberti, 2001).

Organizational changes are stressful for the members of the organization resulting in work related stress, lack for rest and recuperation and sleep and health problems (Greubel and Kecklund, 2011). Anticipated changes had the same effect as actual changes.

Therefore the ability of an organization to deal with changes and hold onto basic values and assumptions regarding safety culture will be vital for long term business survival.

3. METHOD

The effects of new business models in high risk industries will be presented related to some aspects of the safety culture areas as presented in the previous section.

The results presented in the paper have been derived from case studies performed in the railway and aviation domains and are also based on MTO Safety´s extensive experience working in high risk industries. Due to confidentiality issues the observations presented are anonymous.

4. RESULTS

4.1. Safety as a fundamental value and priority

Studies from the aviation domain show that safety can remains a stable, basic value at the operational level of a high risk industry in times of change.

However, the same study showed that basic values on senior management level seemed to have shifted towards cost reductions and economy. This effect seems to be more salient when senior management is less knowledgeable about the operational level.

As for the railway domain, observations indicate that for the operational staff, extensive pressure on cost effectiveness and production, may challenge safety as a core value and basic assumption. Operational decisions drift towards giving higher priority to keep the production ongoing rather than to adhere to safety rules.

There are several examples from aviation and railways, of members of the organization perceiving that core values are shifting from safety to economy and cost reductions. It is perceived that senior management communication and behaviour emphasizes cost effectiveness rather that safety and quality.

The management task in times of change is to improve effectiveness and revenue in a short time span. In many cases the downward communication from senior management emphasizes cost reductions rather than safety and quality. Members of the organization may become confused regarding what the core values are related to safety.

This confusion seems to more salient in organizations coming from a long period of stable external demands and entering a period of changes aiming at mainly cost reductions without systematically including improvement of safety and development of work processes.

The nuclear sector has now entered a situation with major rapid changes and focus on cost reductions and can therefore expect that safety as a fundamental value can be challenged. A major task for senior management is to communicate and uphold safety culture in times of change. The quote below illustrates this challenge.

”achieving safety under deregulation is a particularly demanding task that requires intensive management skills and dedication … safety can be managed even under deregulation. But it takes total commitment, special know-how, a highly disciplined work force and exemplary skill by management.” (Neuschel, 1988, page 109).

The consequences of not managing safety culture as a core value and priority in times of change is that the safety margins are reduced and decisions are taken at all levels of the company based on costs reductions as the first priority and safety and quality is given lower priority.

4.2. Management commitment and leadership skills

Introduction of new business models are driven by changes in external demands and in most cases demands on cost reductions and efficiency. Results from a questionnaire study has shown that staff members most often perceive that high level management give higher priority to economy and to cost reductions than to safety. The same study showed that high level management perceive that they give equal priority to communicating safety and economy.

The results illustrate that senior level management in times of change does not show enough commitment to safety to support the basic safety values. This may affect the decision making process on all organizational levels. There are several examples of decisions being taken leading to major accidents or events where the decision to reduce minor costs will lead to major losses. Examples from the nuclear domain are decision on reducing test programs when installing new equipment in nuclear power plants in order to cut costs. Another example is the decision to reduce testing on the cement job on the blow out preventer leading to the Deepwater Horizon accident (e.g. Hopkins, 2011).

Various studies (e. g. Arvidsson et al., 2006) have also shown that high level management perceive safety culture as better than staff members on lower levels of the organization. These results show that the perception of management and staff on safety culture differs.

It is therefore important that management understands that the cost reduction messages sent out in times of change are very powerful in challenging the safety as a basic organizational value. Therefore management must develop their skills in continuously communicating the safety message in times of change and to repeatedly monitor how staff members perceive the safety message. Safety as a core business value must therefore be made more salient in senior management communication.

Examples of improved ways of communication are making management visible to the staff and increase communication and follow up. Storytelling where past, present and future is explained is a powerful tool (e.g. Packer, 2016).

Safety culture will be challenged when the organization is exposed to a major negative event. When a company faces a crisis such as being involved in a major accident senior management has to take systematic and active measures to uphold safety culture and restore self-confidence in the organization. If a major accident happens senior management must provide a common story to explain the causes of the accident, measures taken and restore self-confidence in the staff members. An important task for managers is to explain this event to the staff, in order to debrief, cope, communicate and restore the organizational balance and self-confidence. It has been observed, both in the aviation and maritime domain that as companies lose self-confidence after a major event, safety as a basic value will be challenged.

4.3. Trust and just culture

Among airlines it has been observed that lack of trust and just culture prevents pilots from reporting safety occurrences. It is suggested that this is related to the management style being too focused on cost reduction, not considering its consequences (Jorgens et al, 2015).

Business models and management styles that involve blame culture may result in crew members not reporting occurrences or being afraid to report safety issues that have been observed.

Also, changes in behaviour where pilots not acting on pilot authority in situations where such action is called for has been observed. Some airlines´

management styles include blame culture, for example by non-renewal of contracts when staff legitimately applying safety procedures and according authority. Such management styles are in total contradiction with safety culture as well as provisions and regulation on Crew Resource Management (CRM) and Safety Management Systems (SMS).

The European Aviation Safety Authority (EASA) calls for effective means of ruling out the possibility of a management style overruling provisions and regulations on CRM and SMS. It has been suggested that this can be achieved by regulations addressing management styles and safety culture.

4.4. Learning

In situations with cost reductions the learning abilities of the organization may be impaired. Observations from organizations introducing new business models have shown that cost reductions in many cases will remove opportunities for informal learning and exchange of information by reducing opportunities and arenas where staff members can meet and discuss in order to improve their work process. For example meetings where knowledge and interpretation of new rules can be discussed and meetings where staff members in different locations can learn from each other are reduced.

Also, new business models and cost reduction puts more focus on reactive learning, where only occurrence reports are used for learning. Also, systemic views on safety and performance are not applied. There is no process for ensuring learning from best work practices. If learning is mostly based on reactive practices it will impair the organizations ability to develop resilience capabilities (e g Hollnagel et al, 2011, Lindvall et al., 2015).

Impaired learning processes can also be related to complacency where a good safety level is taken for granted and the need for safety improvements is not identified.

Also, extensive subcontracting and procurement will result in information and learning not being shared and forwarded to the client. Extensive use of subcontracting will also lead to loss of competence in the client organization.

A phenomena that impairs the learning process has been observed. It can be defined as an explanatory culture meaning that the organization wants to give up their own sense of accountability by trying to whitewash their own involvement and accountability related to negative events and criticism. Such a disinclination to acknowledge and analyse important events will severely impair the organizations ability to learn. Other characteristics are to seek out explanations and confirmation on why change is not necessary.

It has also been observed that subcontractors are reluctant to report occurrences for different reasons. One reason may be in fear of losing a contract and another that a new business opportunity has been identified. Management has to be vigilant on these issues and for example have a systematic process for monitor and collect report from subcontractors. Thus, enhancing the competence level and learning within client organizations.

4.5. Accountability and the effects of outsourcing and subcontracting

New business models in railways and aviation include extensive use of outsourcing and subcontractors in order to reduce costs by procuring products and services. In order to be competitive many suppliers try to reduce costs by changing work hours, employment condition etc thus leading to impaired work conditions. This will affect human performance, e.g. work hours leading to inadequate rest and recuperation will impair performance.

Accountability will be discussed related to the client and the subcontractors. It has been observed in both railways and aviation that the number of subcontractors can be very large, in some cases more than ten levels of subcontractors. In the railway domain the infrastructure manager is required by European directives and national legislation to assure that all subcontractors are working according to the requirements in the infrastructure managers Safety Management System (SMS). Many mangers state that control in cases with more than ten levels of subcontracts is not achievable.

In procurements many clients rely on formal contract terms. However, it is difficult to manage such a contract in times of change where contracts and terms can get outdated quickly. Therefore the client and the supplier must continuously monitor and manage the contracts in order to change and redistribute accountability and activities.

If there are many levels of subcontractors this is a major task and almost impossible to monitor. In for example the aviation domain it has been observed that when the number of interfaces to be managed becomes so many that it will get very expensive to subcontract. Also, when the number of hand over points increases the number of errors related to communication and hand over will also increase. Also, not sharing learning and occurrence reports in several layers of subcontractors will impair learning.

In the aviation domain tightly coupled, interacting computer networks supplying services to airports as well as to air traffic control, can be managed and maintained by several different companies creating numerous interfaces. There are examples where a business model with several low-cost subcontractors can turn out to be much more expensive due to the need for managing risks on numerous interfaces. Other negative effects are social dumping by external contractors and loss of competence if procurement requirements are not taking quality and safety issues into account.

The privatization of the UK rail network is very complex and involves many companies. Many sources believe that the privatization of the rail infrastructure management led to the deterioration of the tracks and was potentially the cause of a several fatal crashes.

In summary, high risk industries are complex systems. New business model increases complexity by adding more subcontractors. Rapid rate of change will reduce control in such systems.

4.6. Communication

Communication has been discussed previously, in relation to management commitment, learning etc.

4.7. Working conditions, work processes and equipment

New business models in the airline industry introduces new hazards related to different employment models, increased mobility of pilots, safety-critical services provided by non-certified service providers and long term leasing. Longer work hours, increased insecurity in employment and reduced social security due to flagging out of airlines to low cost countries ("rule shopping") has been the effect.

In many cases the subcontracting trend among airlines makes the pilots employment status versus the airlines so weak, that pilots often refrain from acting upon their authority with regard to flight safety regulations and issues (e.g. illness, fatigue and fuel) (Jorgens et al, 2015).

Examples from both the aviation and railway domain show cost cutting, shortage of staff and lack of replacements in case of absences lead to staff in safety critical positions perceive pressure to go to work even when they are sick.

Examples from the Swedish railways shows that after deregulation and privatization there are major differences between companies with regard to working conditions, retirement age and work organization.

The new business models means higher workload and clear cut backs related to the employees working conditions. Thus, there is an increased risk that higher work demands and cut backs on resources will lead to an unbalance between demands and resources the resulting in impaired work performance, stress and health problems among employees in safety critical positions. The slack in the demand-resource balance is reduced thus making the organization less resilient.

4.8. Safety culture and the management of change

New business models means rapid changes in goals and mission often related to increased competitiveness and cost reductions. In high risk industries where management focus is on economy story and not paying enough attention to the messages related to safety and quality. In our experience, major changes related to deregulation and cost reductions are often done too fast without adequate planning and preparation resulting in lack of control of the consequences as well as inadequate control of the interfaces have to be managed. There are many examples where control of safety and quality are having a negative effect on safety as well as on business performance. Therefore, programs and skills for managing changes are particularly important in high risk industries.

A change process is stressful for the organizations and its members and in turn concerns of the members of the organization must be manage in order to uphold safety and performance in times of change or crisis.

Operational staff in high risk industries are more resistant since their safety work is based on procedure and technologies where deviations may result in accidents. These organizations are therefore more resistant to changes (Arvidsson, Johansson, Ek & Akselsson, 2006). Introducing changes in these organizations to cope with rapid changes in external demands is therefore more difficult. Communication, participation and trying to achieve consensus is therefore important for a successful change in this organizational culture.

Therefore change management in safety critical industries has to be directed towards developing and refining work processes focusing on safety, quality and efficiency. Change management must be done by use of a systematic process.

5. CONCLUSIONS

The paper has presented challenges to safety culture when introducing new business models in high risk industries such as transportation. These businesses have gone through major changes related to cope with market requirements, regulatory demands and new legislation.

The changes have challenged safety culture and affected the interaction between the Human, Technical and Organizational systems. It is likely that the changes in general have or will have a negative effect on the organizations safety performance.

The nuclear industry is presently facing many challenges and there are important lessons to be learned from transportation and other areas of industry.

In conclusion, focus on safety culture and HTO interactions are essential in order to ensure nuclear safety and cope with the challenges ahead. A strong, solid and sustainable safety culture will be a necessary investment in order to manage changes in a complex system. The nuclear industry must have a clear strategy for development of safety culture in a period of change. This means that the international community as well as the national regulators must set and enforce a clear performance standard related on managing safety culture in times of change. In addition, safety must be explicitly included in the core business values.

The rate of change in high risk industries has to be controlled and managed. Rapid changes in high risk industries will lead to increased complexity and possible loss of control.

Stakeholder requirements and external demands will be important to ensure nuclear safety in the future. Management and leadership knowledge and skills on safety culture will be essential to manage nuclear safety in a life cycle perspective.

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CURRENT APPROACHES OF REGULATING RADIOLOGICAL SAFETY OF MEDICAL AND INDUSTRIAL PRACTICES IN ROMANIA

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Abstract

According to provisions of the Law 111/1996 on the safe deployment of nuclear activities, republished, the practices require an authorization issued by CNCAN, prior to practice development.

1. NATIONAL GENERAL REQUIREMENTS (ACCORDING TO DIRECTIVE 96/29/EURATOM)

1.1 Fundamental norms for radiological safety

The principal document regulating the radiological safety of ionizing radiation application is the Fundamental Norms for Radiological Safety.

These norms set up the requirements concerning the assurance of radiological safety of occupational exposed workers, population and environment, in accordance with the provisions of Law 111/1996 on the safe deployment of nuclear activities, republished.

These norms apply to practices which involve the risk of exposure to ionizing radiation emanating from:
artificial sources;
natural radiation sources in cases where radionuclides are or have been processed in view of using their radioactive, fissile or fertile properties;
electrical equipment which operating at a potential difference of more than 5kV emit such radiation.
also apply to activities which involve the presence of natural radiation sources, in other situations leading to a significant increase in the exposure of workers or members of the public.
also apply to intervention in case of radiological emergencies, or chronic exposure resulting from a radiological emergency or a past or old practice or work activity.

1.1.1. Justification of practices

All new practices which lead to exposure to ionizing radiation shall be justified in writing by their initiator, underlining their economic, social or other nature advantages, in comparison with the detriment which they could cause to health. CNCAN authorize these practices, provided that consider the justification as being thorough.

1.1.2. Optimization of practices

The applicant, respectively the authorization holder, has to demonstrate that all actions to ensure radiation protection optimization are undertaken, with a view to ensure that all exposures, including the potential ones, within the framework of practice developed are maintained at the lowest reasonable achievable level, taking into account the economic and social factors - ALARA principle.

Specific provisions are set in order to ensure that radiological safety principles are integrated into all the activities, and that safety is a clearly recognized value.

1.1.3. Limitation of doses and dose constraints

- Dose limits for exposed workers The limit of an effective dose for occupational exposed workers is 20 mSv in a year. There are also available limits on equivalent dose.
- Special protection during pregnancy and breastfeeding provisions are set.
- Limits of dose for population is 1 mSv in a year.
- Dose limits for the trainees are also set.
- Specially authorized exposures In exceptional circumstances, excluding radiological emergencies, CNCAN may authorize individual occupational exposure of some identified workers exceeding the effective dose limit.
- Exposure of the population as a whole CNCAN take all measures to ensure that the exposure of population to radiation, caused by the nuclear practices, is kept as low as reasonably achievable, the economic and social factors being taken into account. General requirements for to the medical surveillance of the occupational exposed workers are also set. The significant increase of exposure due to natural radiation sources is identified through measurement and verification, consequences are evaluated.

2. SPECIFIC REGULATIONS DEVELOPED FOR MEDICAL AND INDUSTRIAL ACTIVITIES AND PRACTICES

2.1. Norms on operational radiation protection for the development of the Non-Destructive Testing practice with the ionizing radiation

Norms apply to the those NDT practices, which involve the risk of exposure to ionizing radiation arisen from the use of the devices, that contain sealed sources, x-ray generators, and electron accelerators.

There are provisions on the Operational Radiation Protection System, describing the organization structure, and clearly indicating the authority and responsibilities for radiation protection and radiological safety.

The licensee shall establish and implement a training program2 that includes the description of the system radiation protection operational procedures, the risk on the human health associated with the deployed activity, significance of the warning means3, instructions on the use of installations and dosimetric monitoring devices4 etc.

2.2. Radiation safety norms in radiotherapy practice

Norms are applicable to the human medical radiotherapy practice, involving the risk of ionizing radiations exposure, when using the radiotherapy equipments.

The norms cover all the situations when occuring medical exposure, occupational exposure, public exposure, including potential exposures. They state detailed requirements on radioterapy practice, in completion on the Fundamental Norms for Radiological Safety requirements.

According to the provisions of the norms, every medical unit where radiotherapy is performed, a safety culture shall be implemented, in order to encourage an active attitude5 and the wish to learn how to improve the safety and radiation protection knowledge6 and to discourage the self-complacency7.

In order to comply with these requirements, the authorization holder shall draw into an effective safety and protection policy8, especially at managing level and shall effectively and actively support the persons with radiation protection responsibilities[9].

This commitment shall be expressed by a written policy statement stipulating the main importance of radiotherapy protection safety and emphasizing that the

[2] B5. Management assures that there is sufficient and competent staff (GS-G-3.5)

[3] D.5 Work processes are well understood by all individuals (GS-G-3.5)

[4] C.3. There is a high level of compliance with regulations and procedures (GS-G-3.5)

[5] E.1 A questioning attitude prevails at all organizational levels (GS-G-3.5)

[6] E.7 There is a systematic development of staff competencies (GS-G-3.5)

[7] B.6 Management seeks the active involvement of staff in improving safety (GS-G-3.5)

[8] D.3 Documentation and procedures quality is a management concern (GS-G-3.5)

[9] B5. Management assures that there is sufficient and competent staff (GS-G-3.5)

main aim is the medical treatment and the patient safety10. This policy statement shall be known by the management of the medical unit, by the medical personnel11 and has to be followed by a radiation protection program (PRP) that shall include a quality management[12] program (PMC) and by maintaining a safety culture in the institution.

2.3. Norms of radiological safety on diagnostic and interventional radiology practices

Norms detail and complete the basic requirements for radiological safety established in “Radiological Safety Fundamental Norms”, and other applicable national norms. Nevertheless, the norms cover all occupational, public, and medical, including potential exposure situations.

In these regards, in every facility in which diagnostic and interventional radiology practices are in use, a safety culture is to be implemented and maintained in order to encourage an active and learning attitude to protection and safety[13] and to discourage complacency[14].

To comply with this requirement, the licensee shall be committed to an effective protection and safety policy, particularly at managerial level and by clear demonstrable support for the persons with direct responsibility for radiation protection[15].

Commitment shall be expressed in a written policy statement that clearly assigns prime importance to protection and safety in the radiology services, while recognizing that the prime objective is the medical diagnostic, health and safety of the patients. This policy statement shall be made known to the medical personnel and shall be followed by establishing a radiation protection programme (RPP), which includes a quality assurance programme (QAP)[16] and by fostering a safety culture in the hospital. Nevertheless, the main responsibility for the application of the regulations belongs to the legal person (registrants or licensees).

[10] A2. Safety is a primary consideration in the allocation of resources (GS-G-3.5)

[11] C.2. Roles and responsibilities are clearly defined and understood (GS-G-3.5)

[12] D.2 Consideration for all types of safety, including industrial and environmental safety and security, is evident (GS-G-3.5)

[13] C.5 Ownership for safety is evident at all organizational levels and by all individuals (GS-G-3.5)

[14] B.10 Management seeks the active involvement of individuals in improving safety (GS-G-3.5)

[15] D.7 Working conditions regarding time pressures, work load and stress are of management concern (GS-G-3.5)

[16] C.3. There is a high level of compliance with regulations and procedures (GS-G-3.5)

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REGULATOR SAFETY CULTURE: A CONCEPTUAL FRAMEWORK FOR ENSURING SAFETY IN THE NUCLEAR INDUSTRY

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Abstract

Regulator safety culture is a relatively new area of investigation, even though deficiencies in regulatory oversight have been identified in a number of public inquiries (e.g. Piper Alpha, Deep Water Horizon). More recently the IAEA report into the Fukushima disaster specifically identified the need for regulatory bodies to have a positive safety culture. While there are clear parallels between duty holder safety culture and regulator safety culture there are also likely to be differences. To date they have been no published studies investigating regulator safety culture. In order to develop a framework to understand regulator safety culture the researchers conducted a literature review and interviewed safety culture subject matter experts from a range of HRO domains (e.g. offshore oil and gas). There was general consensus among participants that regulatory safety culture was an important topic that was worthy of further investigation. That there was general agreement that regulatory safety culture was multi-dimensional and that some of the elements of existing safety culture models applied to regulator culture (e.g. learning and leadership). The participants also identified unique dimensions of regulator safety culture including commitment to high ethical standards and transparency. In this paper the researchers present the results of the interviews and a model of regulator safety culture. This model will be contrasted with models being used in the nuclear industry. Implications for assessing regulatory safety culture will be discussed.

1. INTRODUCTION

Safety culture is well recognized as a critical component of organizational safety. Culture has been referenced in numerous reports investigating the cause of accidents in high-risk industries (e.g., [1], [2], [3], [4]). Although debate exists regarding a single definition and approach to assessment, it is well recognized that an organization's safety is a complex and dynamic phenomenon consisting of the interrelated functioning of human, system, and technological factors.

A recent report published on the Fukushima Daiichi accident highlighted the importance of considering the safety culture of industry regulators [2]. A number of weaknesses in regulatory functioning were mentioned in this report and considered as contributing factors to the power plant's lack of preparedness in responding to the disaster. Suggestions to mitigate these issues included: "in order to ensure effective regulatory oversight of the safety of nuclear installations, it is essential that the regulatory body is independent and possesses legal authority, technical competence and a strong safety culture" (p. 7). The present venture aims to develop a framework representing regulator safety culture. In order to ensure a strong regulator safety culture it must first be understood what this phenomenon looks like and examples of cultural manifestations. This investigation utilized interviews with safety culture experts from a range of industries to develop a framework of regulator safety culture and understand the best approach to safety culture assessment.

2. LITERATURE REVIEW

Interestingly, to date, there has been limited research published on the safety culture of regulating authorities. In a search of various terms related to regulator safety culture across academic and practitioner reports (see Appendix A), results returned only one article that attempted to define the culture of the regulator. Reiman and Norros [5] conducted a case study on a regulatory authority in Finland, adopting the competing values framework (see Cameron & Quinn [6]) to conceptualize the organizational culture. Using a multi-method approach of surveys, interviews, and workshops, Reiman and Norros [5] classified the regulator's culture as hierarchical, a culture characterized by concerns for long-term stability, predictability and efficiency and one in which procedures govern what people do. This study provided valuable insight regarding regulator culture and the complexity of regulatory functioning. This investigation, however, was of limited scope, focusing on a single organization and investigating the broader organizational culture as opposed to safety culture.

Excluding the one article on regulator culture, the majority of research returned in the literature search focused on best practice of regulatory functioning, including how regulator authorities can best impact licensee safety culture (e.g., [7], [8]). The relative lack of reports regarding the safety culture of the regulator is likely due to the recency of this notion. Consequently, the present study attempts to address this paucity of information by defining the concept of regulator safety culture and developing a regulator safety culture framework.

3. METHOD

3.1. Interviews

Interviews were conducted on different days over the course of 4 months (October to January). At the beginning of each interview, the participant was provided an informed consent form detailing voluntary participation, study content, and confidentiality of the data (see Appendix B). This information was explained in detail by the interviewer and participants were given the option to refrain from participating. Prior to participation any questions were answered and participants were asked additional verbal consent before audio recording commenced. Thirteen one-on-one semi-structured interviews were conducted to investigate employee perceptions of senior manager safety commitment. Interview content included roughly 30 minutes of questions regarding regulator safety culture (see Appendix C). An interview guide was used during interview sessions to ensure consistency in interviewee experience (see Appendix D). At the end of each interview session participants were thanked for their participation and told they may contact the researcher with any additional questions or comments.

3.2. Participants

Thirteen participants from around the globe were recruited for participation in a study about regulator safety culture. Participants were employed as academics or practitioners in a variety of industries and each had extensive experience and/or knowledge of safety culture.

3.3. Materials and measures

Interviews were conducted by telephone and recorded using computer audio recording software. Written notes were recorded during the interview using a laptop computer.

3.4. Procedure

A participant solicitation list was compiled by identifying safety culture experts through publications, practice, and asking safety professionals for recommendation of names. Participants were contacted by e-mail by the researchers and arrangements were made to complete a telephone interview. Upon completion of the interview by the second author and audio recordings were sent to a transcriptionist. On return, the second author ensured any identifying information was removed from reports and supplied the documents to the first author. This step was completed due to the first author’s pre-existing relationship with many participants.

3.5. Data saturation

This study followed principles outlined by Francis et al. [9] to ensure the participant sample resulted in data saturation. The authors state that data saturation occurs when "no new themes, findings, concepts, or problems, [are] evident in the data" (p.4). The exploratory nature of this study supported initial use of a sample of 10 participants. The researcher reviewed notes and audio recordings after each interview and again upon receiving the transcribed text files. Analyses of ten interviews were conducted and similar themes and ideas were grouped together. Consistency in ideas and themes suggested data saturation and three additional interviews were conducted ensure no further ideas or themes were described. At this point the researchers were confident that saturation was met.

3.6. Ethics

The proposed study involved no direct threat or risks to participants. Participants were informed that participation was voluntary and that they may withdraw at any time. To ensure participants felt comfortable with the anonymity of their individual responses all interviews were conducted by a second author who had no pre-existing relationship with any participating members. In addition to this, all transcripts were de-identified to ensure the first author would not be able to determine the source of the data. The researcher's contact information and contact information for the Saint Mary's University research ethic board was supplied to participants in case any questions or issues arose after interview completion. The Saint Mary's University research ethics board provided ethical approval for this study.

4. RESULTS

The purpose of this investigation was to conceptualize regulator safety culture by interviewing professionals in a range of industries with an expert knowledge of safety culture. Results from interviews provided information concerning the most appropriate title for this construct, how this construct may be defined, the impact of regulator safety culture on licensees, how this construct can be represented (dimensions of regulator safety culture), and how this construct may be assessed.

4.1. Naming the construct: Regulator safety culture

This paper adopts and promotes use of the term regulator safety culture. It should be noted, however, that there has been debate about the most appropriate term for this concept. This debate is partially attributable to the various definitions of safety culture. For example, an extensive review identified 18 definitions of safety culture and climate, demonstrating the variability in how this construct is described [10]. Thus, depending on the definition used, the title regulator safety culture may or may be perceived as appropriate. For example, ascribing to the popularly used definition by the British Health and Safety Commission's Advisory Committee for Safety in Nuclear Installations [11], the term regulator safety culture does not seem well suited to industry regulators. The definition states:

"Safety culture is the product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety programmes. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures" (p. 23).

This definition is focused on the safety functioning of an individual organization. Industry regulators must consider their own safety culture, within their operating organization, but also the safety culture of the industry and licensee organizations. Thus, the absence of focus on safety culture of external operations makes the term regulator safety culture unsatisfactory.

Adopting a slightly different definition of safety culture, the term regulator safety culture is more acceptable: "…that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance" [12]. Using this definition, regulator safety culture may be more easily assumed to include the values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety programmes in addition to safety functioning of the regulated industry.

Discussions with safety culture experts produced mixed results regarding the most appropriate term for this construct. Select participants described that the term regulator safety culture is not suitable because the regulator's role is to ensure that industry is complying with regulatory frameworks. Additionally, a few participants described that the term safety culture is too specific and limits the scope of characteristics that can impact the regulator functioning. Due to these factors, a number of participants stated that the term regulator culture is more appropriate, as this term represents the organizational culture of the regulator.

In contrast to these findings, other participants contended that it is critical to include the term safety in the construct title to ensure the maintenance of appropriate focus. Participants also described that due to variations in definitions of safety culture, the title of this construct should not be an issue of focus. Instead, focus should be placed on conceptualizing the construct by establishing well-founded dimensions of safety culture.

In short, the term regulator safety culture has faced debate and scrutiny in our discussions with safety culture experts. Considering this, we find it important to recognize the issue and provide reasoning for adopting the term. The term has been adopted for the following reasons:

- Previous use of the title in published reports
- Maintaining safety in the title name to promote a focus on safety
- Suitability of term when adopting the INSAG-4 (1991) [12] definition of safety culture
- Promoting focus on the conceptualization of the construct instead of semantics

4.2. Defining regulator safety culture

Responses regarding the most appropriate definition of regulator safety culture were mostly consistent. Participant descriptions of regulator safety culture related to how the regulator thinks and acts with regards to safety, and included descriptions such as:

- "…it's kind of how the regulator thinks about the task of regulating… The nature of safety and the way of effectively interacting with the regulated parties. So those to me have to do with cultural values and cultural assumptions and that is the culture part of the regulator that I would want to think about and speak to. So I think regulator safety culture at least in that context to me, indicates that is a regulator that is centered and focussed on safety as a primary function."
- "…it represents well, what either a regulator or licensee must do to actually have appropriate safety attention."
- "…I don't think it differs too much internally to the safety culture of any organization and how that safety culture influences how they interact with their stakeholders, is an interesting one and certainly you could almost say it's their mindset…"
- "Well particularly how important the regulator feels safety is in the overall activity that they are regulating. The safety and reality for them."
- "It's how the imagined object of safety is articulated through what the regulator does […] not exactly what they do but instead the imagined object architecture of it that's implied by what they do."

Considering participant statements and previous definitions of safety culture, the present study defines regulator safety culture as:

the product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of their approach to the regulation of industry safety.

To better understand the concept of regulator safety culture, participants were also asked to describe "dimensions" or "characteristics" of regulator safety culture. These findings are discussed below.

4.3. Dimensions of regulator safety culture

Participant's descriptions of the dimensions of regulator safety culture were aggregated to identify the following five dimensions (Fig. 1), represented by employees' shared value for:

(a) Leadership commitment to creating a positive safety culture
(b) Proactive, risk informed and flexible approach
(c) Continuous learning and self-improvement
(d) Unwavering ethical standards
(e) Transparency through communication

A small number of participants stated that regulator safety culture is equivalent to safety culture of licensees, and thus, an already established framework could be used to represent regulator safety culture. Others proposed that because the regulator functions to ensure safety of the industry and is not a high-risk organization, safety culture manifests differently, and therefore requires a framework unique to the regulating authority. The five themes provided in this document were carefully constructed from participant suggestions, including statements of dimensions and comparison with already existing frameworks (e.g., [13], [14]).

4.3.1. Leadership commitment to creating a positive safety culture

Participants described management's leadership as a critical aspect of regulator safety culture. For example, one participant stated:

"Good management is the key to everything […] good management is key to having a good culture […] good management in terms of making sure that people are not overworked and not put under enormous amounts of pressure for the kind of things they have to do… That they have deadlines that are actually manageable, that their managers make decisions and help out."

FIG. 1. The five dimensions of regulator safety culture. The dimension of leadership drives the remaining four dimensions.

In summarizing participant statements, this dimension of safety culture was characterized by leaders' promotion to ensure the regulator: (a) adopts a proactive approach to the development of industry safety, (b) is committed to continuous learning and self-development, (c) maintains ethical practice, and (d) is transparent in all activities. Moreover, one participant stated the importance of leaders maintaining a focus on safety: "a strong safety culture is one in which the leaders demonstrate that safety is their overriding value and priority. […] the leaders must be talking about it and be seen to, with sincerity, believe in safety."

Consistent with organizational theory [15], participant descriptions referenced that leaders create and shape culture within the organization. The importance of leadership in shaping safety culture is represented in pre-existing frameworks of safety culture (e.g. [13], [14]). Interestingly, however, these frameworks represent leadership as a singular dimensions of culture. That is, leadership is listed alongside other dimensions of culture and there is limited discussion of the interrelated nature of leadership in all aspects of organizational functioning. The present framework proposes that leadership is a higher order dimension that shapes all other dimensions of culture. As depicted in Fig. 1, leadership is represented as an overarching dimension that subsequently impacts the four interior cultural dimensions. Presenting the model in this manner emphasises the importance of leadership in shaping regulator safety culture including the necessity for management to maintain beliefs and values related to the four inner dimensions.

4.3.2. Proactive, risk informed and flexible approach

A shared value for a proactive approach to industry regulation was characterized by two defining themes: the regulator's mentality toward regulation and the way in which the regulator approaches regulating activities. The two themes are intricately related; the regulator's mentality toward regulation undoubtedly influences the approach it engages in. The following sections describe these themes in more detail.

With respect to the regulator's mentality toward industry regulation, participants described that the regulator's perceived responsibility for industry safety combined with the regulator's view of licensees are components of the regulator's safety culture. The way in which the regulator perceives its role in industry safety was described as a continuum ranging from a perceived responsibility to ensure compliance versus a perceived responsibility to continuously improve industry safety. In essence, regulators may fall anywhere on the continuum, but a strong safety culture was described as being focused on continuous improvement shaped by research, collaboration with external agencies, and a coaching style of management. Comparatively regulators with a limited view were said to focus solely on compliance. Furthermore, a regulator with a strong safety culture was described to be able to guide licensees in safety development while maintaining awareness to not overstep boundaries. This included maintaining an awareness of the licensee's culture, abilities, and expertise of operations. As one participant described, the regulator should know its place and know that it's role is not in the control room:

"…going back to Three-mile Island as an example, when the [regulator] got involved too much into the hands-on event response in the control room, this is an example of a regulator's direct safety culture impact on the licensee. So it's up to the licensee to figure his own solutions they're the expert to run or save the plant. The regulator shouldn't be in the control room to pull levers."

In line with how the regulator views licensees, participants described that regulator safety culture is characterized by the way in which regulator employees think individuals behave with respect to rules and punishment. The belief that employees in licensee organizations are best regulated through the sole use of rules and punishment is representative of a limited view of regulation and consistent with a weak safety culture. Contrarily, participants stated that maintaining a belief that behaviour is shaped through leadership characterized by constructive feedback and contingent reward is related to an expanded view of regulation and a stronger safety culture.

In addition to how the regulator thinks about its role in industry, participants described that the approach used in regulating licensees is an important part of the regulator's safety culture. Participant statements included whether the regulating agency engaged in strict enforcement of compliance (prescriptive approach), coaching and collaboration (performance approach), or a willingness to engage in either approach when needed. One participant described the two approaches as follows: "on the one hand there is the mutual respect and partnership philosophy and on the other hand there's the policeman philosophy." Statements referencing the function of the regulator also described the importance of maintaining a human approach in regulation. This includes regulator members having a conversation with licensee members without paperwork and structured assessments: "a good regulator will also be able to, you'll be able to meet the person over a cup of coffee, have a discussion without any notes being taken, papers shown, in order to reach a clear understanding." Another participant stated: "…I think that good regulators […] spend as much time doing off the record stuff as they do on the record stuff." Similarly, participants described that the extent to which employees believe that paperwork is sufficient to understand and manage licensee functioning is a characteristic of culture. For example: "the extent to which they believe that the paperwork is sufficient. In other words, the paperwork as opposed to what's actually happening on the ground…" In line with the notion of a human approach to safety, descriptions indicated that a strong safety culture is supported by leaders and employees who ensure accuracy of information and who do not rely solely on paperwork as an indication of licensee functioning. The importance of being risk informed was also described as a characteristic of regulator safety culture. This included perceptions related to the value of understanding industry risk and risk within licensee organizations and the efforts made to identify and assess risks. For example, in explaining dimensions of regulator safety culture one participant stated "…the primary is the understanding of the nature of risk of the industry that they are regulating."

In addition to this, participants described the importance of striving for continuous improvement. In line with this, a value for innovation and experimentation was mentioned: "what's the value of innovation and experimentation? …is this seen as something that is good for learning or is it seen as something that's bad for safety?" In short participant responses reflected that a strong safety culture is characterized by the maintenance of a proactive approach to industry regulation that maintains a priority for safety using evidence-based approaches and utilizes a balanced approach to regulation that best meets the needs of the licensee.

4.3.3. Continuous learning and self-improvement

In descriptions of safety culture, participants referenced the importance of a shared belief in continuous learning and self-development. This included employee's perceived value for and openness to learning combined with a perceived value for being risk informed. Descriptions that referenced the importance of learning included regulators being open to: learning from experience, learning from other regulatory and industry experiences, audits and assessments of regulatory functioning, and collaboration with industry experts to ensure continuous self-development. For example, one participant stated: "you have to have a way of learning from experience, learning from other people's experience. You have to have a system for making sure that you are not creating the same problems for yourself again and again". Value for learning was also described as the regulator's openness to collaborating and learning from others: "…[it is] important for [the] regulator to make sure all parties are present around table to bring solutions to nuclear safety, globally. [… it is] about leadership and partnership."

Participants described the criticality of competence as a component of regulator safety culture. This included competence of the organization at an industry level (understanding of industry risk), operator level (understanding of operations) and individual level (competence of inspectors). For example, one participant stated: "I think competence of employees, both theoretical and practical is key to how well the regulator works." Similarly, one participant stated:

"…and what is competence? To do this and to measure this and to make a difference with it, you've got to define it. So you've got cognitive competence, which is the knowledge. You've got the functional competence which is the skill set or the ability enact the knowledge in physical terms… but then you've got the wider organizational culture that has you set up to be able to give you the means to display that, and to keep up to date. So educational opportunities, systems that support what you're asking people to do."

Thus, descriptions indicate that maintaining an awareness of the limits of competence at all levels of regulatory functioning, and working to continuously learn are important functions of regulator safety culture.

4.3.4. Unwavering ethical standards

A shared value for upholding ethical standards was described as another dimension of regulator safety culture. Maintaining a value for professionalism in all conduct within the regulating organization and in work with external agencies (licensees, stakeholder organizations, government) was described. Discussion of unwavering ethical standards was often referenced with respect to external influences that can impact regulatory decision-making, including political pressures, pressures from societal culture, and threat of residential safety or security. Participants stated that regulators need to be aware of and able to withstand these types of external pressures. One participant stated:

"how to think of the national nuclear infrastructure and how things are influencing each other in ways, in intended ways but very often in unintended ways and dynamic ways that is hard to foresee […] and that is also difficult to formalize to have lots of people thinking of that and talking to each other."

Similarly, one participant described that the way in which the regulator reacts to external pressures is an indication of its safety culture: "how does the regulator react to the public and under political pressure and how independent is it?" Extending on this notion, participants discussed the importance of regulator independence. In order to maintain ethical standards participants stated the regulator must maintain independence from government and other external parties. For example, some participants warned that a relationship between the regulator and the licensee can compromise ethical practice whereby "too cozy a relationship between the regulator and the regulated" can lead to questionable practice. These statements highlight the importance of the regulator acting in collaboration with external agencies but maintaining strong, independent leadership guided by ethical practice.

Ethical practice was also described in terms of the regulator's expectations. Participants stated that the regulator should live up to the standard that it sets for licensees and should lead by example. This included descriptions of maintaining fair expectations; in other words, not expecting the licensee to operate in a way the regulator would not. In sum, upholding ethical standards (e.g., professionalism and fair expectations) in the face of external pressures or influences was described as an important part of regulator safety culture.

4.3.5. Ensuring transparency through communication

A shared value for maintaining transparency in regulatory functioning was also described as a characteristic of regulator safety culture. Transparency was described as the regulator's communication of internal processes to keep parties (regulator employees, licensees, public, government, stakeholders) informed on regulatory decision-making and action. In turn, participants described that transparency of functioning fosters industry safety development through shared learning.

In addition to the importance of maintaining transparency in regulatory functioning, participants described the significance of the regulator's ability to successfully communicate this information. Participants stated that the regulator must be able to communicate with external parties in a rational and scientific manner. That is, the regulator must be able to convey sensitive regulatory processes in a manner that appropriately relays the information and does not foster the development of premature conclusions. For example, one participant described that:

"…the regulator now that some intolerance of let's say risks or perceived risks, this is rapidly become an exercise of PR and it shifts the message into everything you say: everything is safe, everything is safe, without having the capacity to say yes, it is safe, they've been operating safely however, they need to fix A, B, C and D because they are having issues and struggles here and there. We are at that place now where we are caught between a rock and the hard place and that is becoming as systemic issue and it's a capacity to report issues of performance in transparent manner without jumping the guns to the necessity of closing the plant."

Moreover, participants also described the importance of transparency within the regulator. That is, management and employees within the regulator communicating about processes to promote best functioning and development of industry safety. Participants described the importance of employees using means beyond those built within the organization to ensure information sharing (e.g., making an effort to speak with colleagues to share pertinent information versus relying on data-sharing from spreadsheets). Additionally, participants described the importance of continuous feedback within the organization to reduce the potential for miscommunication. In sum, participant statements demonstrated that communication about regulatory processes to external parties and within the regulatory body are important aspects of regulator safety culture.

4.4. Assessment

There was unanimous agreement among participants regarding the merit of assessing regulator safety culture. Participants stated that assessment is critical to the development of industry safety, and one participant claimed that in the wake of the Fukushima disaster, there exists an obligation to assess safety culture to prevent similar accidents from occurring. Although participants agreed in the merit of assessment, there was variance regarding the best approach to assessment. A majority of participants agreed that a multi-method approach whereby data is triangulated would best support cultural measurement. For example, one participant stated:

"…it's a good idea to use combination and triangulate as much as you can to interview people but also look at management system. What do they actually say they are supposed to do, see how they comply, see how well they understand it and analyze it from different perspectives to get the whole picture of how things are in that way…"

Furthermore, participants claimed that qualitative methods would provide the best cultural insight due to the thoroughness of these techniques. Suggested methods involved evaluation of employees at all levels of the organization (e.g., frontline staff to senior management) and included on-site observations, document analyses, interviews, focus groups, and questionnaires. Many participants suggested using questionnaires as a preliminary measure to provide initial insight into cultural functioning and to provide areas of focus for incorporating other measures (e.g., developing interview questions). Limitations of safety culture questionnaire use were described by several participants and included issues with social desirability and issues with reliability during statistical analysis (e.g., factor analysis). Subsequently, participants described that observational and qualitative methods made up for the weakness of questionnaires, reinforcing the use of questionnaires as a preliminary or supplementary assessment tool. Descriptions of organizational factors that may be considered for assessment of regulator safety culture are provided in Appendix E.

Participants also described the utility of involving internal and external parties in cultural assessments. This was described as a method that would mitigate bias and enhance the interpretation of findings and organizational development. One participant stated:

"…so the self-assessment is there for the discovery journey and it's the same philosophy we're applying to our licensee. It's key and important. You must do self-assessment because it takes you through a journey of discovery. Mainly the interviews, right? What would be great about that self-assessment, is to have external participants that brings you a vision that you may not have on your own self."

Furthermore, one participant described the utility of having a C.E.O from another organization involved in the assessment process. This participant noted that when discussing findings from a cultural assessment, the participating C.E.O could provide input and relay the findings to executive management in the organization of interest. Using an external executive member would challenge the executive team of the organization under assessment and foster discussion due to a shared understanding of executive level processes.

Additionally, several participants noted the importance of how the results from regulator safety culture assessment will be used, including the willingness of different regulators to use and share information to further industry development. For example, one participant stated:

"I mean what would be the point of measuring it and where would you see the measurement process going? So, if it's not to learn and share and inform and develop then, I mean maybe that could happen internally but I think there would be a certain amount of resistance to a wider learning process".

Another participant echoed this notion, stating:

"[regulators] in my experience tend to be pretty hierarchical in the way people are sort of trained, decisions are made and things and have a, to the safety culture review you have to cut you know across and down and […] I'm not sure that senior regulators think the views of the people along or below them really matter, so I think, to undertake such a study of a regulator I think for many regulators it will be very challenging because they're unused to anyone challenging their position."

Last, a small number of participants described the importance of considering the perspective of the licensee in assessing regulator safety culture. One participant described that to ensure the regulator safety culture has a positive impact on licensee operations, it is critical to include the licensee in assessment:

"…you would have to look at it also from the perspective of the licensees because in the end you wouldn't really know how they responded to certain types of regulation until you watched how they responded. In the end they are the people controlling safety so you would have to look at both. To do a job on this properly

[…] you would have to assess both. The likes of the regulators' intentionality […] and how the licensees responded."

In short, it is apparent that assessment of regulator safety culture is a worthwhile venture, however, a multi-method approach using in-depth investigative techniques is suggested to adequately evaluate the construct.

5. IMPORTANT CONSIDERATIONS

Discussions with participants provided substantial insight into the concept of regulator safety culture. In addition to this information, participants described a number of potential challenges that should be considered when investigating this construct.

As previously mentioned, participant responses were varied regarding use of the term regulator safety culture. While some supported use of the term, others felt that regulator culture or regulator organizational culture is more appropriate. It is therefore important for practitioners and researchers to recognize this disagreement and provide evidence for the adopted term in order to mitigate confusion or disagreement.

Participant concern for regulators' openness to assessment was also mentioned. As described, due to the regulators position of power, some participants stated the entity may be less inclined to undergo assessment and use the results to inform decision-making. This potential issue should be considered in practice and methods put in place to ensure regulator management appreciate the value of assessing and developing regulator safety culture.

Another important factor to consider when dealing with regulator safety culture is the impact of external bodies on regulatory control. Participants described that there exists a political domain that can impact regulator functioning and thus, its safety culture. Similarly, participants described that societal culture can have a drastic impact on regulatory functioning; participants noted that regulators in different countries will function according to their cultural norms. It is therefore important that practitioners attempt to identify political and societal influences in order to best navigate safety culture development.

The impact of individual differences was also described as a potential challenge in regulator safety culture development. Participants described that individuals inside the regulator can view their roles differently. For example, one participant described this as:

"…many people inside the regulator community see their roles as differently. I see mine is about zero accidents, zero injuries, zero fatalities, zero environmental degradation. So compliance is only part of what you do in order to drive to zero and I think a lot of regulators see their job as basically just being watchdogs."

Another participant described the issue of individual variance in terms of inspectors:

"…I know from experience that different inspectors can have very, very different approaches so it does depend on the individual inspector and it does depend on the relationship they have with the industry and with the companies that they are regulating within that industry."

This issue of different approaches within the regulator reinforces the importance of management within the organization driving a strong and cohesive culture that approaches regulation based on the individual needs of a licensee. Thus, practitioners should be aware of management functioning in assessing and developing regulator safety culture to ensure all levels of employees are being led appropriately.

Last, participants described that the advancement of safety culture within industry and academia is impaired due to a lack of validity in published documents. One participant stated that a greater focus on the validity of measures must be maintained in safety culture research. Thus, efforts should be made to ensure that measures developed and used in safety culture assessments are put through rigorous validity testing.

6. CONCLUSION

In summary, the present venture provides initial insight regarding regulator safety culture. Responses from safety culture experts highlight that a strong regulator safety culture includes a shared value for a proactive approach to industry safety, continuous learning and self-development, unwavering ethical standards, and transparency of organizational processes. Most importantly, regulator safety culture was described to be shaped by leaders within the organization who maintain and promote these values. Assessment of regulator safety culture was described as an important and useful venture that requires a holistic, multi-method approach utilizing descriptive techniques (i.e., qualitative methods). Last, participants mentioned a variety of challenges that can impact the success of regulator safety culture and its assessment that should be considered by parties interested in regulator safety culture development. In closing, the present investigation is a first step in defining and conceptualizing regulator safety culture. The next stage of research continues by developing a regulator safety culture perception survey that can be used as part of an assessment process.

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APPENDIX A

Literature Review Search Terms

Regulator Safety Culture

Regulatory Safety Culture

Regulator Culture

Regulatory Culture

Regulator Organizational Culture

Regulatory Organizational Culture

Regulator Organizational Climate

Regulatory Organizational Climate

Regulator Safety Climate

Regulatory Safety Climate

Regulator Safety Culture White Paper

Regulator Culture White Paper

Regulatory Culture White Paper

Regulator Organizational Culture White Paper

Regulatory Organizational Culture White Paper

Safety Culture Regulation

APPENDIX B

Informed Consent Form[17]

INTRODUCTION

Dr. Mark Fleming and his research team at Saint Mary's University invite you to participate in a study aimed at understanding and assessing industry regulator safety culture.

Participation in the study is voluntary and involves participating in an interview with a research member. You will be asked to provide opinions related to industry regulator safety culture and how this construct may be assessed. Information will not be linked with your name and results will be aggregated with other participant data to identify constructs representative of regulator safety culture. You are free to withdraw from the study without penalty before January 1, 2016. After this date data analysis will have begun and it will be impossible to identify or remove your individual information from the study. If you choose to withdraw, any information gathered will be destroyed and will not be included in the study.

PURPOSE OF THIS RESEARCH

The purpose of this research is to improve understanding and develop a perception survey of industry regulator safety culture.

WHO IS ELIGIBLE TO TAKE PART?

This study targets English speaking professionals with an expert knowledge of safety culture and/or industry regulators.

WHAT DOES PARTICIPATING MEAN?

You will be participating in a 30-minute interview with a researcher regarding your opinion of industry regulator safety culture. The interview will occur after you have completed the signed consent form and asked any questions you have. Participation will include thinking about the concept of regulator safety culture, identifying dimensions of this construct, and discussing assessment strategies. You will also be asked to provide your current position and length spent in this position.

WHAT ARE THE POTENTIAL BENEFITS OF THIS RESEARCH?

[17] Researcher contact information has been removed in the published report

There are no direct foreseeable benefits with participating in this study. Participating in this study will contribute to organizational and academic understanding of industry regulator safety culture.

WHAT ARE THE POTENTIAL RISKS FOR PARTICIPANTS?

There are no foreseeable risks associated with participating in this study. If an adverse experience occurs during or after the interview, you can contact Dr. Mark Fleming at [redacted] or [redacted] or Dr. Jim Cameron [redacted] or [redacted] for assistance.

WHAT WILL BE DONE WITH MY INFORMATION?

Your name and contact information will only be used for the purposes of conducting the interview. This information will be used to schedule a time for you to participate in the study and send relevant research materials. With your permission your name will be included in the acknowledgements of the summary report and publications. Your individual responses will remain confidential to the research team. Audio recording and written documentation will be used to complete an academic report and provide information to the investigating organization (the IAEA). Your personal information will not be directly connected with your responses; responses will be anonymous in any and all research papers, publications, and communications with your organization.

All information collected in this study will be stored on password-protected computers and will only be accessible by the research team members and professionals hired to transcribe material. Your information will not be shared with anyone else. Data will be stored for 5 years before being destroyed.

HOW CAN I WITHDRAW FROM THIS STUDY?

Participation in this study is completely voluntary. You have the right to participate or not, and if you choose to participate, you can withdraw from the study at any time during your interview participation. Withdrawal may be completed by requesting to skip interview questions or by notifying the interviewer that you do not wish to continue. It is important to note that once data analysis has begun (January 1, 2015) it will be impossible to remove your responses. Your responses will never be linked with your name and always remain unidentifiable.

HOW CAN I GET MORE INFORMATION?

Information or questions regarding this study may be requested at any time from Kate Bowers at [redacted] or Dr. Mark Fleming at [redacted] or [redacted]. If you have any questions or concerns about ethical matters, you may contact the Chair of the Saint Mary's University Research Ethics Board at [redacted] or [redacted]. This research has been reviewed and approved by the Saint Mary's University Research Ethics Board.

Notice of Agreement

Consent for participation may be indicated by e-mailing [redacted] the following text:

I understand what this study is about, appreciate the risks and benefits, and that by consenting I agree to take part in this research study and do not waive any rights to legal recourse in the event of research-related harm.

I understand that my participation is voluntary and that I can end my participation at any time without penalty.

I have had adequate time to think about the research study and have had the opportunity to ask questions.

By sending this e-mail I consent to participate in Dr. Mark Fleming's study aimed at understanding and assessing industry regulator safety culture.

Please keep a copy of this form for your records.

APPENDIX C

Interview Questions

1. What is the title of your current position?
    a) How long have you been employed in this position?

2. As a concept, what is your understanding of regulator safety culture?

3. Is regulator safety culture the most appropriate term for this construct?

4. Are you aware of any research that has been conducted on this topic?

5. What are the dimensions of regulator safety culture?
    a) Please classify these dimensions in order of importance (most important to least important).

6. Is there merit in assessing this construct?
    a) How might regulator safety culture be assessed?

7. How does regulator safety culture influence member organizations (i.e. licensees)?

APPENDIX D

Interview Plan

Written consent will first be sought using signed consent forms approved by the Saint Mary's University Research Ethics Board.

Introductory Script: Hello, and thank-you for agreeing to participate in this interview. Your input is a valuable asset to this research venture. My name is Kate Bowers and I am part of a researcher team at Saint Mary's University investigating industry regulator safety culture. I would like to remind you that your participation is voluntary, and you may chose to end your participation in any time. You may also feel free to skip any interview questions you do not wish to answer. Your individual responses will be treated as confidential and your personal information will never be directly connected with your responses. Information you provide will be used in an academic report and aggregate data will be relayed to practitioners to help them understand and assess regulator safety culture.

Discuss the utility/focus of interview:

- Explain why/how it is a valuable tool for collecting data
    - In this research venture interviews will allow us to gain more in-depth information regarding industry regulator safety culture. Using a one-on-one discussion facilitates a comfortable environment with the flexibility required to garner answers to our research questions.

Discuss logistics of the session:

- Length of interview: 30 minutes
- Break available on participant request

Inform participant that audio recording will now commence:

- Ensure participant is comfortable and consents to recording
- Commence audio recording

Ask participant if he/she has any questions before starting:

— Address any questions

Commence interview questions:

— Follow interview guide

Conclude Interview:

— End audio recording
— Thank for participation
— Address any remaining questions
— Read out feedback form and discuss content on form (i.e., how to withdraw, how to acquire research results).

APPENDIX E

Participant Descriptions of Regulator Safety Culture Indicators

The following list presents participant descriptions of organizational factors thought to be indicative of regulator safety culture. Participants stated that these factors may be assessed in order to form an understanding of the regulator safety culture:

- Observations and assessment of what employees say
- Observations and assessments concerning what employees do
- Management systems
- Employee training programs
- Incentives and reward structures
- Performance agreements
- What is Written/Published (style, tone)
- Conferences Attended

PRODUCT SAFETY CULTURE: A NEW VARIANT OF SAFETY CULTURE?

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Abstract

Product safety culture concerns the organizational culture that affects the integrity and reliability of products and services and thus the safety of those using them. This is a new topic within the sphere of safety culture which has been adopted by manufacturing companies, e.g. in the food and defense sectors. The paper introduces the concept of product safety culture with reference to the available literature and then examines reported cases of product failures where the investigation has considered organizational precursors. Product safety culture seems to be a variant of safety culture that weighs particular cultural dimensions. These might be worthy of additional emphasis when managing worker and process safety. The dimension in particular that would merit exploration in product safety culture would be safety systems. Safety systems refer to organizational safety policies and procedures that are enacted through worker safety behaviors that may have an impact on product integrity, as considered in the accidents described in the paper. Research is required to examine the impact of product safety culture on product safety outcomes (e.g. failures) and to determine to what extent typical safety culture dimensions could be replicated in this aspect of culture, and whether novel dimensions should be considered.

1. INTRODUCTION

Safety culture can be defined as a set of shared attitudes, values, beliefs and practices held by an organization in terms of safety and effective control [1]. It is a product of organizational intelligence and safety imagination [2]. The term was first introduced within the nuclear industry after the Chernobyl nuclear power plant accident in April 1986. Investigators attributed the incident to an organizational culture that led to inappropriate workplace safety practices relating to the plant operation [3]. Since then, safety culture guidelines have been established for the nuclear power industry (e.g. International Atomic Energy Agency (IAEA) [4]) to encourage the adoption of management systems and practices that should facilitate a culture that will enhance both worker and process safety. In the last 30 years, there has been a significant research effort across higher risk industries to determine the key dimensions of safety culture that have most influence on safety outcomes [5], [6], [7].

Recently, several manufacturing industries, in particular the defence and food sectors [8], have started considering aspects of safety culture that are oriented towards the safety of the product and service users. The reason for this is to establish to what extent the user's well-being could be affected by the organizational safety culture.

Product safety culture is therefore a new research area which concerns consumer safety rather than worker or process safety. Product safety, as defined by one defence company focuses on avoiding "unacceptable harm to any third parties or the people using them [products]. No complex and innovative product, whether used in defence or civilian markets or both, is without risk" [9] (p. 45). The consequences of failing to manage hazards and risks appropriately could result in user harm or death. It is therefore important to be able to manage the risks within a product's lifecycle [10], which consists of four parts: 1. as designed, 2. as built, 3. as maintained and 4. as operated. Overall, product safety applies to a wide range of goods that are used by specialist practitioners or by the general public, such as food, drugs and vehicles. Product safety also applies to the provision of services, such as for patients using a healthcare system; there is now an extensive literature on hospital (or patient) safety culture (e.g. Waterson [11]), with some evidence that the cultural factors that influence worker safety are similar to those influencing patient safety [12]. All these domains of safety can be considered as applications of consumer or product safety in ensuring that harm to the user is avoided or mitigated.

Product safety failures can have legal consequences relating to a manufacturer's liabilities in the event of an accident. In safety-critical products, such as equipment used in the nuclear industry, military or the oil and gas sector, the scale of impact in case of a failure tends to be larger than day-to-day product faults which affect only one or more users. In the high hazard sectors, product failures could result in a wide impact on the environment and members of the public.

There is no clear understanding of how an organizational focus on product safety affects workplace processes. For instance, how do company policies and practices influence the determination of product safety and affect workers and managers' perceptions of what are acceptable risks for users?

The paper will attempt to establish how product safety culture should be defined and whether it is a variant of safety culture in general. An examination of some major product safety failures will illustrate which aspects of organizational culture were implicated. The established safety culture dimensions will be examined to see whether they could also underpin product safety culture. In future research, these dimensions can be tested to measure their impact on product safety behaviours of workers or on product safety outcomes (e.g. failures and malfunctions of products; user injuries and fatalities). As product safety concerns the technical failures of products, a more technical approach might also be relevant to the nuclear industry, given recent suggestions for further consideration of technical systems within nuclear safety culture [13].

2. PRODUCT SAFETY CULTURE

Despite 30 years of inspiring and engaging research in the field of safety culture, it is time to reconsider whether the findings fully encompass the concept. The focus on product safety culture in manufacturing industries may reveal facets of culture that have not been traditionally emphasised. This could result in more attention being paid to aspects of safety culture that are concerned with hazardous impacts on those outside of the organization. Traditionally, safety culture research and practice has concentrated more on internal outcomes.

Product safety culture can be defined as a set of attitudes, norms, beliefs and behaviours of employees that affect the integrity of a product as a result of existing safety practices. This working definition has been adapted from the broader safety culture definition as a set of shared attitudes, values, beliefs and practices held by an organization in terms of safety and effective control [1]. It is firstly necessary to consider the origins of product safety culture by looking at several product failures where organizational culture has been implicated.

2.1. Product safety culture failures and incidents

There have been several high-profile product safety failures that demonstrated how a poor safety culture could have affected the state of the goods and services used by the specialist groups or by the general public. Selected cases are the Nimrod aircraft explosion, the Takata airbag scandal, the Toyota accelerator problem and the Volkswagen emissions fraud. These examples of poor product safety culture and associated product failures are briefly described in order to identify issues of organizational culture implicated as causal factors.

2.1.1. Nimrod

The concept of product safety culture appears to have emerged after the investigation into the Nimrod aircraft accident [14] which echoed aspects of NASA's Challenger and Columbia reports [15], [16]. The culture at NASA and its contractors deteriorated and damaged product safety, resulting in user fatalities. This accident was a result of a blend of human and organizational failures.

The RAF Nimrod XV230 incident on 2nd September 2006 was a mid-air explosion of a military aircraft over Afghanistan that resulted in 14 fatalities. This was due to ignition of leaking fuel as it came into contact with engines located in the wing of the aircraft, turning a regular refuelling task into a catastrophe. Haddon-Cave [14] noted failures in leadership and organizational safety culture led to the Nimrod incident. The aircraft exploded due to several serious technical failures, preceded by deficiencies in the safety case and a lack of proper documentation and communication between the relevant authorities. Implicated in the event were the UK Ministry of Defence, the Royal Air Force and two UK defence contractors, QinetiQ and BAE Systems. According to Haddon-Cave [14] (p. 473), *"the ownership of 'risk' is fragmented and dispersed"* and there is *"a lack of clear understanding or guidance as to what levels of risk can be owned/managed/mitigated and by whom"*. This points to deficits in communication and in safety systems practices where objectives and reports were unclear and thus, parties involved felt they did not need to engage in risk assessment as the general consensus was that the aircraft was operationally safe.

After his assessment of the Nimrod incident, Haddon-Cave [14] advised the re-organization of military aviation safety regulation by appointing senior officers to assess airworthiness and safety-related issues, stressing the need for accountability and clearly organized responsibilities and approaches. Consequently, the UK Ministry of Defence established a Military Aviation Authority (MAA) in 2010. Maintenance policies and engineering manuals were reviewed as a result of the Board of Investigation's recommendations. Also, a forensic teardown was carried out to thoroughly examine the remainder of the Nimrod fleet to ensure no other hazards were present.

To summarise, the Nimrod incident was a result of poor safety culture that through its complacency in leadership, communication and safety systems affected the product integrity and safety, resulting in its failure. In Haddon-Cave's [14] (p. 403) words, *"these organizational failures were both failure of leadership and collective failures to keep safety and airworthiness at the top of the agenda"*. In order to be able to understand the interplay between organizational culture, safety culture and the technology – in this case the aircraft and its airworthiness – it is necessary to consider the engineering aspects of managing risk within a safety culture.

2.1.2. *Takata*

Product safety is important in day-to-day life, where a product failure as a result of poor organizational safety culture, can cause user harm or death, as in the case of Takata airbags scandal in 2015. Due to car airbags exploding on impact, eight people died and others were injured [17]. Due to this, large-scale recalls were issued worldwide, with 54 million vehicles recalled [18]. According to the investigation reports, this was due to the Japanese company's safety malpractices of fixing faulty airbags and installing them in vehicles. Takata apparently conducted secret tests to assess the integrity of their products, then deleted the data and denied that the safety issues were a result of the company's cost-cutting policies. *"Takata tentatively concluded that a compromised seal on the inflator or an overloading of propellant into the inflator might have caused the rupture. Honda said it was assured by Takata in 2004 that this incident was an anomaly."* [17] (p. 3). As such, organizational culture, specifically the applications of safety culture, can have far-reaching consequences beyond the workplace of an organization and affect the safety of a product.

In the case of the Takata airbags, the failures were related to a lack of management commitment to safety where there was clear involvement of upper management in controlling the data released to the public and its manipulation within the organization. Additionally, communication was an issue as line managers in their manufacturing plants attempted to control the situation, where workers would often repair a damaged airbag on the manufacturing floor as opposed to discarding it or assembling it appropriately. Overall, the general cost-cutting and pressure for production resulted in non-adherence to manufacturing standards and thus in producing faulty products, implying poor execution of safety systems.

2.1.3. *Toyota*

In an earlier automobile case, the Japanese car manufacturer, Toyota paid 1.2 billion US dollars in a criminal settlement with US prosecutors in 2014 for covering up severe safety problems with *"unintended acceleration*," and continuing to make cars with parts Toyota *"knew were deadly."* (according to the Federal Bureau of Investigation). The most dramatic of the accidents occurred in 2009 when a highway patrolman Mark Saylor and three members of his family were killed after the accelerator in his Toyota Lexus car had become stuck on an incompatible floor mat. He called the emergency services while his car was speeding at over 100 miles per hour and explained his ordeal right up until the crash that ended his life. A series of other accidents relating to unintended acceleration in Toyota cars resulted in the investigation.

In a deferred prosecution agreement, filed in 2014, the company admitted that it *"misled U.S. consumers by concealing and making deceptive statements about two safety related issues affecting its vehicles, each of which caused a type of* *unintended acceleration." Toyota "put sales over safety and profit over principle,"* according to FBI Assistant Director George Venizelos accusing the company of disregarding public safety. *"Not only did Toyota fail to recall cars with problem parts, they continued to manufacture new cars with the same parts they already knew were deadly. When media reports arose of Toyota hiding defects, they emphatically denied what they knew was true, assuring consumers that their cars were safe and reliable… More than speeding cars or a major fine, the ultimate tragedy has been the unwitting consumers who died behind the wheel of Toyota vehicles."* [19]. As in other cases, the implication is that the company culture valued profit before consumer safety and consequent decisions and actions contributed to the dangerous products. The company had to recall 8.1 million vehicles for safety checks.

2.1.4. Volkswagen

In 2015, a vehicle emissions testing station in the USA reported that some diesel cars from the German manufacturer, Volkswagen, contained hidden software (a defeat device) which detected when the car was undergoing an emissions test and significantly reduced the normal emission volume. It transpired that as a particular engine could not meet the US emissions targets, a group of employees had fitted the engine with software to give two different emissions readings. While no direct user injuries were ascribed to this practice, the effects of exhaust emissions can contribute to harmful air pollution.

The ensuing adverse publicity resulted in the company recalling 11 million cars and experiencing reduced sales. Volkswagen managers subsequently admitted *'that there was a culture of rule-breaking being tolerated within certain areas of the company that led to the misconduct and shortcomings of individual employees and weaknesses in some processes'.* [20]. Senior managers, who claimed to be unaware of the software modification, resigned. The company, who had long traded on their safety reputation, were described in the media as having a 'cynical attitude' to consumers and their wellbeing. Internal investigations within the company are ongoing, as are a number of legal actions from consumer groups.

2.2. Learning from product safety failure cases

The cases above all come from transportation, where the risks of a faulty vehicle causing injuries and fatalities are relatively high but there are further product safety scandals from other types of goods. A common theme from the investigation of these events is that aspects of the organizational culture, whether in the private or public sector, have contributed to the flaws in the product and that these often relate to prioritising other goals over consumer safety. Aspects of leadership and communication and attention to standards have also been questioned in the investigative reports. In the following section, we examine the more general cultural literature on worker and process safety to identify organizational factors which may be of particular influence.

3. WORKER AND PROCESS SAFETY IN SAFETY CULTURE

Existing research in worker and process safety culture has examined specific dimensions and measured their effectiveness in relation to recordable safety outcomes and worker safety behaviour. It is worth remarking that there have been a number of dimensions identified (such as work pressure, risk, boundary management), but in the last decade, there has been a move towards unifying these dimensions into three or four ‘core’ categories. The main cultural dimensions appear to include management commitment to safety, safety systems and communication, as extracted from several studies [5], [6], [7].

The question is whether the same cultural factors could affect product safety? It appears from examining the product safety literature that there may also be the need to involve the aspect of technology (such as equipment used to manufacture a product or a service) in safety systems when considering the manufacture and usage of products. In general, there should be more emphasis on safety systems in product safety (procedures, policies and necessary training governing worker behaviour and technical understanding) as this would more accurately explore and reflect highly developed technical environments. Perhaps this also applies within safety culture in general to ensure safe and efficient productivity of an organization through good understanding and appropriate safety practices and operation of relevant equipment. As such, due to the impact of human behaviour on product safety, it would be pertinent to examine whether the dimensions relevant to worker and process safety culture are also components of product safety culture. Overall, broadening the insight into safety systems perspective would be critical in high reliability organizations to mitigate further accidents and improve the overall safety culture of an organization, such as in the nuclear industry.

Additionally, management commitment to safety should not be considered separately within the organization but rather integrated into the aspect of safety systems. The reason for this is that management commitment to product safety is a result of organizational safety culture policies (therefore derived from safety systems) that focus on appropriate worker practice and procedures. Furthermore, communication should be involved in the consideration of safety systems – even though a separate dimension, it would be integral in facilitating information exchange, especially between management and sharing appropriate safety systems practices.

To summarise, product safety culture should be considered as a result of the interplay between human factors and technology (e.g. work equipment used in product assembly) affecting the organization’s safety culture to determine whether its influences could impact product safety through human behaviours and practices.

4. TECHNOLOGY AND PRODUCT SAFETY CULTURE

4.1. Technology and design

Similar to the conclusions of the IAEA [13] report on the Fukushima Daiichi NPP accident in 2011, Rollenhagen [21] argued that to consider safety culture in its full scope, one would need to be more understanding of the underlying technology as an influencing factor. While this is usually accounted for, his main argument was that safety culture could become a catchphrase for human factors related issues only and not a concept of its own. The importance of technology and design has been downplayed by focusing on improving and adapting human behaviour to work around the technology in terms of carrying out complex processes through the use of relevant technical systems. Innovation of technology is critical in making systems safe and also relates to understanding and progress. While innovation is risky as individuals would be dealing with unknown factors, Rollenhagen [21] proposed that some risk-taking in this area would help adapt systems to humans as opposed to only adapting humans, producing an unbalanced management style.

With innovation, technological design would be more resilient which would result in less safety-oriented behaviour that would require management. He pointed out that for this idea to work, people would have to 'go out of their comfort zone'. Based on the Principles of a Strong Nuclear Safety Culture [22], there is a more apparent move in terms of understanding that nuclear technology may be more complex to operate, which in turn facilitates focus and need for improvement in the technical systems and their usability.

There should be a balanced focus between human behaviour concepts and technology as both of these factors are subsumed within the larger organizational conceptual categories. Effort should be made to understand how these elements underpin a specific culture without using linear thinking, but rather assuming that safety is systemic [21]. This would also reshape thinking about accident causation which could be influenced by existing safety culture. Pidgeon [2] had suggested that attention to safety culture may shift focus away from some risks, such as technology and its innovation, as well as from the understanding of complex technical systems. While Leveson [23] argued that a complete understanding of complex technical systems was not possible, there should still be a balance established between human behaviour and having a clear understanding of the operating technology in terms of purpose and its risks. As such, human behaviour should not be looked at in isolation from the technical aspect of a system but as a part of it. Ideally, this should be reflected in the culture questionnaires and other methodological approaches. This approach could be helpful in cases like the Nimrod, where there was lack of clarity and transparency in terms of the suitable upgrades carried out on the aircraft. Additionally, this approach might be relevant for understanding the Fukushima

Daiichi nuclear power plant accident where the incident occurred due to insufficient awareness of the nuclear power plant's resilience.

4.2. Fukushima Daiichi NPP Accident

Based on previous incident reports (such as the Nimrod or the Takata incident), similar dimensions of safety culture can be implicated in the Fukushima Daiichi nuclear power plant incident (NPP) in March 2011 [13]. Additionally, the IAEA report supports the suggestion for an emphasis on the aspect of technology, and thus good knowledge and understanding of safety systems required to run the NPP safely, within an organizational safety culture.

In 2011, the Fukushima Daiichi NPP in Japan suffered several reactor explosions and a radiation release which were triggered by an earthquake and tsunami. The IAEA [13] stated in their incident analysis report of the event that there was a basic assumption that "NPPs were safe, there was a tendency for organizations and their staff not to challenge the level of safety" (p. 67). Additionally, the analysis of human and organizational factors concluded that "in order to better identify plant vulnerabilities, it is necessary to take an integrated approach that takes account of the complex interactions between people, organizations and technology" (p. 67). As such, the evaluation stated that the safety culture was not a continuing process of improvement but was rather founded on the belief that the initial design for this NPP had addressed all the possible scenarios. This relates to the Nimrod accident [14] for example, where product safety was not adequate, as the anticipation and planning for the type of events that led to the incident had not been accounted for. Moreover, there was an underlying belief that the aircraft was essentially safe, and a degree of complacency coloured subsequent decisions and judgements. The Fukushima Daiichi incident is similar in its shortcomings, where the original design of the NPP had not accounted for a natural disaster of the scale that occurred in March 2011. The report of the IAEA international experts meeting in 2013 [24] on the human and organizational factors in the Fukushima accident, states that there was wide recognition of the 'need to guard against complacency.' (p38).

5. DISCUSSION

As stated previously, the analysis of the incident at Fukushima Daiichi NPP in 2011 [13] supports the notion that technology and a better understanding of technical systems and how they may affect human behaviour – therefore not merely moulding the human behaviour to suit the operation of technical systems, but making adjustments in the complexity of technical systems to suit the workers – could have an impact on the state of the organizational safety culture. Considering that product safety culture would focus on the safe operation and use of products, this assumption could be extended to product safety outcomes (e.g. product failures) as well.

In terms of product safety culture and examining relevant dimensions to it, it is necessary to consider the idea that there may be potentially other dimensions related to product safety culture that may not have been perceived as relevant to safety culture in general. Due to the novelty of the research area, as well as the need to validate whether existing dimensions could relate to product safety culture, it will be necessary to carry out research to answer these primary questions before investigating the broader concept of product safety culture.

The aim of our current research is to explore the basic concept of product safety culture and examine to what extent it relates to safety culture and whether it has any distinguishing features. Notably, the dimensions of safety culture are being examined in order to determine whether the 'core' dimensions identified (e.g. management commitment to safety (a result of leadership), safety systems and communication) can also be related to product safety outcomes. These three dimensions have been identified as most relevant in research to date. Additionally, these dimensions have been a focus of two interview studies carried out within the defence sector, preliminary results of which will be discussed at the conference.

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HUMAN AND ORGANISATIONAL SAFETY BARRIERS IN THE OIL & GAS INDUSTRY

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Abstract

Safety barriers are devices put into place to prevent or reduce the effects of unwanted incidents. Technical barriers are one type of safety barrier, e.g. blow-out preventers to prevent uncontrolled release of hydrocarbons from a well. Human operators may also have an important function as an element in organisational safety barriers, and may play a role in preventing or mitigating the effects of major accidents. The paper describes the use of organisational barriers in the oil and gas industry, and presents two oil and gas research projects related to organisational safety barriers.

1. INTRODUCTION

The oil & gas industry is a safety-critical industry where errors or accidents may potentially have severe consequences. Offshore oil & gas installations are complex technical systems constructed to pump hydrocarbons from below the seabed, process them and pipe them to onshore refineries. Hydrocarbon leaks or other unwanted events might have severe consequences to human lives or the environment. The industry must therefore have a strong focus on safety.

The petroleum industry has in recent years had an increased focus on major accidents. Major accidents are defined as "A sudden event, such as a large release of hydrocarbons, a fire or explosion that immediately or later leads to several serious injuries and / or loss of human lives, grave damage to environment and / or a large economic loss" [1]. The Norwegian Petroleum Safety Authority has identified the following as events with large major accident risk [2]:

— Hydro-carbon leakages (oil, gas, condensate)
— Serious well incidents
— Damage to carrying construction and maritime systems
— Ships on collision course

An important tool for ensuring the safety of oil & gas installations and for preventing or reducing the consequences of major accidents is the concept of safety barriers.

2. SAFETY BARRIERS

Principles for the management of safety barriers have been described by the Norwegian Petroleum Safety Authority [1], and are summarised below.

Safety barriers are technical, operational or organisational elements that individually or collectively are intended to reduce the possibility for a specific error, hazard or accident, or that prevent or reduce negative consequences. Barriers have a *barrier function*, i.e. a specific purpose, which is fulfilled by *barrier elements*. In other words, barrier elements are the measures or solutions that are implemented in order to fulfil the function of a barrier. A barrier function for an oil and gas installation may be to "prevent unwanted release of hydrocarbons from the well". A barrier element for this function may be a blow-out preventer valve that will quickly close the well, either automatically or by manual activation.

Each barrier element should have defined *performance requirements* to ensure the barrier's effectiveness, and these can be directed towards e.g. the element's capacity, integrity, reliability or ability to withstand loads. So for a blow-out preventer, there may be performance requirements that state how much pressure it must withstand, or how quickly it is activated.

In the complex setting of an oil platform in operation, barriers may not always work in the optimal way. *Performance-influencing factors* are factors that may influence the performance of a barrier. Such factors may include: the quality of maintenance; or whether the installation is operated according to requirements.

The first step when implementing barrier functions is to identify the potential risks or accident situations that may occur. Then the barrier functions to address those risks should be established, including their barrier elements with associated performance criteria.

2.1. Organisational and operational safety barriers

Human and organisational factors can also be elements in barrier systems. Organisational barriers refer to human operators and their role in detecting unwanted events or their precursors, in responding to them and in mitigating their consequences. [1] A control room operator has the possibility to detect an incident building up, via alarms or other indicators, and to take actions such as activating safety systems. The operator is therefore seen as an organisational barrier. The actual activation by an operator of safety systems or mitigating actions when an incident is detected is defined as operational barrier. When we are talking about organisational or operational barriers, the performance requirements for these may be e.g. competence level, criteria for how actions should be performed, response time, or the availability of personnel [1]. Different factors, such as workload, attitudes, the quality of leadership, and culture, may affect how vigilant personnel are towards specific risks, and how quickly they are able to detect and respond to events. These are therefore performance-influencing factors for the organisational barriers.

3. RESEARCH ON HUMAN AND ORGANISATIONAL FACTORS IN THE OIL AND GAS INDUSTRY

In this section two research projects will be presented, each looking at different sides of human and organisational factors.

3.1. Use of mindful safety practices

The first project used questionnaire data to investigate the use of mindful safety practices (safety-promoting work practices intended to prevent or interrupt unwanted events) at petroleum installations on the Norwegian continental shelf, and factors that may impact employees' willingness to use these practices [3]. The practices aim to increase employees' sensitivity to potentially dangerous situations, to identify the dangers and then to warn against those dangers. The dangers may be related to something other employees are doing, or to potentially dangerous factors in the environment. Examples of mindful safety practices are: warning somebody when you see that a person is in an unsafe situation; to "take two", i.e. take a break to think through the situation when you are facing a potentially safety-critical condition. The author hints to the importance of humans as barrier elements when stating that it is "... reasonable to assume that more danger events will be prevented if employees intervene in situations *where they judge that safety is endangered*, than if they do not intervene in these situations. For this reason, the existence of *MSPs* at the installations and employees' willingness to use them is of critical importance" [3].

The study grouped factors that may influence the employees' willingness to use mindful safety practices into three levels: 1) the individual level (age, experience, health, perceived ability to deal with safety-related issues); 2) the group level (managers' safety attitudes, colleagues' use of mindful safety practices, psychological work environment and task performance environment); 3) organisational level (e.g. perceived risk level, overall work environment, physical work environment)

Among the findings was that employees' willingness to use mindful safety practices was correlated more strongly with factors on the group level than on the individual or organisational level, and this was particularly the case for safety practices directed at other persons. This suggests that use of the practices is influenced by group norms, from having a common sense in the group of how things should be done, through getting feedback from the group and through observing others. Implications from the project are:

If management wants to implement initiatives to increase employees' willingness to use of mindful safety practices, these initiatives should be directed at working groups in their local environment.

The willingness to use mindful safety practices may change if an employee is transferred to a new work environment, or if changes are introduced in a work environment, because other group norms may be in effect in the new or changed environment.

3.2. Defining requirements for and monitoring organisational safety barriers

Over time safety barriers may deteriorate, and it is important to know the status of barriers - to know to what extent they are functional. The performance of barriers should be monitored, managed and if possible improved across the lifetime of the installation [1]. For technical barriers this may be done by use of inspections, condition monitoring and testing. For organisational barriers it may be less straightforward to monitor their status, and it would be useful to have methods for this. An oil and gas research project has looked into how to define requirements for and how to monitor organisational safety barriers against major accidents [4]. The project was based on a review of recent incidents in the Norwegian oil & gas industry, as well as interviews with personnel from the oil & gas industry with competence on major accidents. The purpose was to develop performance requirements to the elements of organisational barriers to ensure the effectiveness of the barriers, e.g. demands to capacity, functionality or reliability. For the treated organisational barriers, performance requirements have been defined and indicators for the performance measures have been developed on three levels of the organisation.

A method for monitoring the organisational barriers was also developed. This method may be applied as a way to proactively monitor parameters that can influence the risk for major accidents in an organisation, to identify developing weaknesses in the barriers. It may also be used to communicate major accident risks across organisations or companies. The latter may be a way for authorities or regulatory bodies to trend major accident risk over time. The method may be a pro-active support to management in understanding the status of organisational barriers, so that adequate initiatives may be implemented to restore barrier functions when needed.

3.3. Relevance for the nuclear industry

The nuclear industry has much in common with the oil and gas industry, as both are highly safety-critical industries. The use of humans as safety barriers is as relevant and necessary in the nuclear industry as it is in oil and gas. The results of the first project, looking at use of mindful safety practices, may not be directly transferrable to the nuclear setting, as the work practices and work environments differ from the petroleum setting. The mindful safety practices do have their equivalent in the nuclear industry in the form of human performance tools [5]. However, there may be a different pattern in what factors affect employees' willingness to use safety practices. It is, though, likely that the influence of group norms on nuclear employees is also present to a certain degree, and that a change in work environment may lead to a change in the safety practices.

The Defence-in-Depth is an important safety concept in the nuclear industry, incorporating the concept of barrier thinking. After the Fukushima accident, the impact of human and organisational factors on Defence in depth has been suggested as an area where further work may be beneficial [6]. Methods for monitoring the integrity of organisational barriers seem to be in demand as in the oil and gas industry, so this seems to be a relevant topic to explore in the nuclear industry, and may also be an area where collaboration across the two industries could bring fruitful results.

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LEARNING LESSONS FROM TMI TO FUKUSHIMA AND OTHER INDUSTRIAL ACCIDENTS: KEYS FOR ASSESSING SAFETY MANAGEMENT PRACTICES

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Abstract

The main objective of the article is to discuss and to argue about transfer from a specific industrial sector to another industrial sector, of lessons learned from accidents. It addresses the following questions: why, what, and how can we better capitalise and use lessons learned from accidents? Attempts of responses will be achieved, firstly through the discussion of some theoretical foundations such as recurring accident patterns whatever the sectors, failures to learn shown by recurrence of similar events, the possibility of capitalising lessons into a knowledge and culture of accidents such as pathogenic organisational factors, and also with the methodological lessons of investigations that helped the development of organisational analysis. Secondly on the challenge of use, some examples of application cases in normal operation for the assessment conducted by IRSN of safety management practices in Nuclear Power Plant (NPP) are provided. Finally, the rationale for using the lessons is stressed with notions as “royal road” and “gift of failure”, and some perspectives and barriers in theory and practice about these transfers are discussed.

1. INTRODUCTION

The nuclear electricity generating industry has faced three major accidents in 30 years (Three-Mile Island in 1979, Chernobyl in 1986, Fukushima in 2011) involving three different reactor technologies operated in three quite different cultural, organisational and regulatory contexts. Each of those accidents has been at the origin of new issues, but also the generator of specific and generic lessons, some changing the worldview [1] about the origins and causes of accidents. Indeed, one can mention that in addition to the engineering view about the importance of technical design, new “paradigms” were proposed such as human performance, safety culture, organisational reliability and sociotechnical interactions.

Other high risk industries have had their major accident cases too in the last decades: e.g. aviation accidents such as Tenerife airport planes crash (1977) and loss of Rio-Paris flight (2009); space shuttles losses with Challenger (1986) and

Columbia (2003); train accidents, e.g. Paddington trains collision (1999) or Brétigny-sur-Orge train derailment (2013); process industries disasters with Flixborough (1974), Seveso (1976), Bhopal (1984), Toulouse (2001), Texas City (2005), Buncefield (2005), or offshore with Piper Alpha (1988), Deepwater Horizon (2010)... Each accident has generated new or recurring issues to be solved especially in their country and industrial sector, and sometimes abroad in the same industrial sector. As it will be detailed later, the systematic study of several industrial accidents shows that similar and transferable lessons could be learned.

This quick overview of the history of industrial accidents shows at least that *there are potentially many lessons available worldwide for safety analysts. The general question to us is: is there a relevant learning potential (for every industrial sector), and if so, can it be better used?*

Therefore, several subsequent questions could or should arise at this stage:

- Are the lessons from accidents fully learned?
- How to go beyond the implementation of lessons case by case?
- Is it possible to use the knowledge of the main case studies of industrial accidents and in what purposes?
- Could this knowledge change our mindset and so, practices of accident prevention and operational safety management?

2. WHY SHOULD WE USE THE LESSONS OF ACCIDENTS BETTER?

Based on our experience and findings, as an answer, we propose three types of weaknesses: inabilities to learn fully the lessons from accidents, inabilities to transfer others' hard lessons, and the limits of safety improvement.

2.1. Failures to learn from accidents

After an accident, an investigation is launched to understand what, how and why it happened this way, to identify the direct and root causes, the lessons to learn, the corrective actions to implement; in order to at least avoid the repetition of a similar accident here (but also elsewhere, as lessons are disseminated).

2.1.1. In the nuclear industry

After TMI, Chernobyl and Fukushima's accidents, thorough investigations were launched by several official commissions (Kemeny, Rogovin, Diet…). Dissemination and treatment of lessons were conducted at national and international levels (e.g. several IAEA reports and workshops, European Union stress tests after Fukushima…). Some lessons were implemented such as improvements of human-machine interfaces, recast of some emergency operating procedures, severe accident mitigation strategies, management provisions and crisis management, remediation of radioactive pollution, strengthening of regulation, "hardened-core" of technical and organisational measures to ensure the prevention and mitigation safety functions…

However, despite strong input and many actors' commitments, one should already notice that some of the available lessons on other **root causes** did not really provide deep changes, such as for organisational complexity, management of production pressures, inter-organisational relationships, regulatory capture, and failure to learn [2,3]… Similar root causes have been found for Fukushima [4, p. 16] showing some barriers to learn from others' hard lessons: "*The operator (TEPCO), the regulatory bodies (NISA and NSC) and the government body promoting the nuclear power industry (METI), all failed to correctly develop the most basic safety requirements.* [...] *The regulators also had a negative attitude toward the importation of new advances in knowledge and technology from overseas"*.

2.1.2. In other industries

Learning from accidents remains difficult not only for the nuclear industry. Among the very high-risk industry of rocket and space, NASA experienced two losses of space shuttle: Challenger in 1986 and Columbia in 2003. Former astronaut Dr. Sally Ride who was a member of both accident investigation teams observed that there were "echoes" of Challenger in Columbia. Indeed, the CAIB noticed that *"The foam debris hit was not the single cause of the Columbia accident, just as the failure of the joint seal that permitted O-ring erosion was not the single cause of Challenger. Both Columbia and Challenger were lost also because of the failure of NASA's organisational system"* [5].

The first idea is that organisational causes were determining contributors to the two accidents. The second general idea is that organisational causes led to similar effects with two space shuttle accidents. These deficiencies to learn and to correct organisational failures have been pointed out by the CAIB: *"First, despite all the post-Challenger changes at NASA and the agency's notable achievements since, the causes of the institutional failure responsible for Challenger have not been fixed. Second, the Board strongly believes that if these persistent, systemic flaws are not resolved, the scene is set for another accident. Therefore, the recommendations for change are not only for fixing the Shuttle's technical system, but also for fixing each part of the organisational system that produced Columbia's failure"* [5, p. 195)].

These are for us key remarks made by the CAIB. *These two accidents are unique events and have very different technical failures but similar organisational causes. The inability to learn and change the organisational system led to similar deficiencies that enabled a similar accident to reoccur.* These remarks are determining lessons for thinking prevention strategies.

A similar phenomenon was observed at BP with the recurrence of several similar major accidents before the Deepwater Horizon disaster (in 2010):

Grangemouth refinery incidents in 2000 in Scotland, Texas City refinery explosion in 2005 and Prudhoe Bay pipelines leaks in Alaska in 2006.

The Baker Panel [6], an independent panel set-up to assess the safety deficiencies in the five US BP refineries after the Texas City refinery accident in 2005, "*noted "striking" similarities between the lessons of Grangemouth and the events of the Texas City explosion, most notably the lack of management leadership, accountability, and resources; poor understanding of and a lack of focus on process safety, coupled with inadequate performance measurement indicators; and untimely completion of corrective actions from audits, peer reviews, and past incident investigations. The Panel concluded that "in its response to Grangemouth, BP missed an opportunity to make and sustain company-wide changes that would have resulted in safer workplaces for its employees and contractors*" [7, p. 142].

In 2006, there were some leaks in BP pipelines in Alaska at Prudhoe Bay. The CSB was asked to compare the 2005 and 2006 accidents although it had not investigated the Prudhoe Bay accident. The CSB former CEO, Carolyn Merritt stated in her testimony to the US House of Representative in 2007 that "*there are striking similarities in the reported causes of the 2006 events involving BP's Prudhoe Bay pipelines and the 2005 explosion at the BP Texas City Refinery. Most if not all of the seven root causes that BP consultants identified for the Prudhoe Bay incidents have strong echoes in Texas City".* She concluded that: *"The CSB report and the Booz Allen report point to similar cultural factors within BP, in both its upstream production and downstream refining operations. The similarity in the two reports underscores how safety culture truly is set at the top at a corporation.*"

One can state that, *after an accident, in-depth organisational learning in the same organisations, in the same industry, and learning fully from others' hard lessons, remains much more difficult than expected.* It seems unfortunately less efficient than regularly claimed.

2.2. Some barriers to recognise the generic character of others' hard lessons

After a major accident, a reactive learning loop is usually performed by the operator, the regulator of the country that often change the regulation for similar systems, and sometimes, the lessons are shared internationally and may lead to design changes (e.g. for airplanes, nuclear reactor), operation and regulatory changes worldwide such as for Fukushima. Those learning loops remain mostly in the industrial sector. Fukushima accident' lessons did not led to changes in aviation sector; and Columbia space shuttle disintegration did not led to drastic changes in process industry in Europe. The main mindset pinpointed here is that other technological failures are too different for presenting a potential to be captured.

Even in the same industrial sector, barriers to learn are seen between competitors in the same country and between countries. That is why regulators from most industrial sectors have pushed for more international exchanges about lessons.

In addition, the major accident is often considered by most safety specialists as *unique*, as it is a specific and contingent combination of multiple causes and circumstances that would hardly repeat itself as such. So the lessons are implemented after each event, on a case by case approach.

According to our analysis, these rationales are not considering as much as they could similarities between countries and industrial sectors. In all cases, the different industrial systems are sociotechnical systems [8]. Beyond the technological differences, people work in organisational settings that can be deficient, and these deficiencies may be worth learning [9, 10]. The regulatory oversight can be similarly failing. In short, the generic character appears clearer at upper levels (work, organisation, control) of the sociotechnical systems. This remark stands despite the fact that lessons can be gathered on technical equipment (e.g. pumps and valves) that can be used in different industrial sectors.

When looking at accidents patterns, beyond the fact that major accidents have multiple causes (direct and root), *recurring schemes* of accidents have been recognised by researchers. Remarkably, the systematic study of industrial accidents since the mid-70 by a few researchers has shown some *generic patterns* in the occurrence of an accident:

- an *incubation period* [11] in which signals alerting of a potential hazard are not recognised and treated accordingly at the proper level; some actors may have recognised these *weak signals* such as *whistle-blowers* but they are not listened;
- *latent errors* that reside in the system for long such as design flaws and maintenance errors with no consequence for a long period of time - they oppose to *active errors* that have rather immediate effects [12];
- the systemic and organisational character of root causes, with notions of *system' failure* [13]; and *organisational accident* [14].

An ultimate consequence is that these notions are setting the foundations of a model and definition[18] of an accident.

In addition, these generic schemes do recur themselves with a similar phenomenology: similar root causes, similar effects. When comparing the Davis Besse nuclear power plant incident and the Columbia accident, the U.S. Department of Energy [17] identified common causes and lessons from the two accidents. When studying dozens of accident thick reports or with more than a hundred studied [18], a disturbing statement finding is that *similar root causes recur across accidents, whatever their occurrence contexts (industrial sector, country, regulation, culture, history).* In other words, *one found "echoes" or "striking similarities" not only in NASA and BP accidents' patterns but in most if not all accidents.* Based on the empirical approach that "the regularities have a sense", this fact opened the way for a capitalisation of generic patterns of accident [2, 3].

2.3. Limits of safety improvement

Although some failures to learn were pointed, one can recognise that equipment reliability and safety management provisions have contributed to the overall risk reduction of the high risk industries that has followed more or less an asymptotic curve for the last 50 years. Industry leaders and regulators often recall such accomplishments that required and still require many efforts, and some may consider and even claim that residual and acceptable risk levels have been achieved.

However, firstly, some limits should be recalled. Improvements are more difficult to observe; some consider that the trend of accidents is steady, more or less the same year after year, *"dancing a tango on an asymptote"* [19]. Major accidents have happened in all industries these last decades. Some accidents recur and their causal analyses show that most were preventable. To conclude, are we missing something that could explain these deficiencies?

Interestingly, Turner [11] does not describe an accident in technical terms but rather in terms of effects on the beliefs of the organisation. He postulates that the last

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[18] "*In-depth analyses of accidents, incidents and crises clearly showed that any event is generated by direct and/or immediate causes (technical failure and/or "human error"). Nevertheless their occurrence and/or their development are considered to be induced, facilitated or accelerated by underlying organizational conditions (complex factors). A vast majority of events can be seen as the ending point of a process of safety degradation. An event is very rarely an "unexpected combination of circumstances" or an "act of God". Indeed, an accident happens at the end of an incubation period (Turner 1978), during which some events and signals (weak or strong) occur, but they are not perceived and/or not treated appropriately according to their potential threat to safety. Every industrial system is coping with factors that impact safety, both positively and adversely. The life of an industrial system, from a safety standpoint, can be seen as continuous tension between resilient organizational factors (ROF) and pathogenic organizational factors (POF). An accident occurs when POFs overtake ROFs* "[15, 16]

stage of development of an accident is a *"full cultural readjustment"* related to their risk perception and their risk management. Then this raises the following question: is or was this readjustment really performed after accidents? To our analysis, we assume that it is not often the case. The strategy we propose relies on a better capitalisation and transfer of lessons learned from accidents.

3. HOW CAN WE CAPITALISE AND TRANSFER LESSONS LEARNED FROM ACCIDENTS?

To address such issues, we present the argument on the theoretical interest of a *new knowledge and culture of accidents* [20]. This concept aims at addressing several goals:

- to ensure a better use of lessons and knowledge gained from accidents,
- to enrich safety analysts, prevention actors and decision-makers with background knowledge references,
- to disseminate and make effective this knowledge (as an alive memory) for operational actors,
- to enable a paradigm shift in the end (more centred on organisational dimensions of sociotechnical systems rather than only or mainly on human errors and technical deficiencies).

The first part of the concept addresses the issue of the content of the knowledge and how lessons from accidents should be capitalised and used by safety analysts. The second part of the concept addresses the challenge of the knowledge transfer to operational actors and ultimately how it articulates with safety culture.

3.1. The medical metaphor to support the proposal to capitalise and transfer of the lessons learned from accidents

The medical analogy has been used for several years in safety and prevention domains to communicate, explain, understand and model accidents and safety (pathogen agent, epidemiological triangle, matrix of Haddon [21]; incubation period [11]; latent errors, resident pathogen and pathogenic factors [12, 14]). However, we insist in our medical analogy on other issues.

In the history of medicine, diseases and pathologies have had a fundamental role. It is by their study, especially the causes of death [22] with the auscultation and the autopsy of bodies, that a specific knowledge of diseases was established. In medicine, one can notice the effort to collect pathologies, to analyse them, to extract generic issues, to classify and to keep memory.

A collection of (reference) cases (in medicine handbook) was worked on and articulated with the support of epidemiological studies to establish the knowledge of diseases. Thus the aetiology of diseases was established as a course and feeds, guides and supports the questioning of the clinician during the diagnosis. In other terms, this knowledge can help to detect early symptoms and diagnose a disease before its acute form shows up. Today, at the medical school, the learning of the reference cases requires a huge (years) effort of memorization for future doctors.

This first analogy enables us to draw the attention on the need of developing an established, articulated and actionable knowledge of accidents.

Secondly, on the side of the diagnosis methodology, the spirit and culture of the medical diagnosis is clinical. It requires using past knowledge accumulated on diseases, to infer clinical signs based on symptoms before deducting the syndromes.

Thus, the investigation in general (before and after an event [23] and more specifically a safety organisational analysis methodology requires a clinical approach of the organisation (witness interviews, document and data records of the system) and a “comprehensive” approach [24, 25, 26]. It should address the historical context and the organisation dynamics. The organisational diagnosis is therefore guided by accumulated knowledge of *organisational accidents* [14] or *system failures* [13]. The recurring accident influence factors or *pathogenic organisational factors* are guiding the identification of probable organisational vulnerabilities [23, 24, 25, 26, 27]. It should be noticed that the organisational analysis approach was framed with some of the methodological lessons of exemplary investigations such as the ones conducted by the Columbia Accident Investigation Board (2003), the Chemical Safety Board investigation on Texas City refinery explosion (2005) and the trains collision at Paddington (U.K.) that was conducted by Lord Cullen (2000) [28].

3.2. Principles for the development of the new knowledge of accidents

Firstly, past accidents have a fundamental importance for the *structuring of the knowledge* because they provide detailed accounts. These *thick descriptions* (in the meaning of the anthropologist Geertz [29]) feed the library of cases. Accidents are not “cold cases”, as they should be revisited with new insights. Indeed, a new accident could help to understand better grey areas of a previous one, to confirm or to invalidate previous assumptions, and to identify repetitive factors or configurations and even generic patterns. This permanent review should be organised cross-industries and internationally as well on accidents as on crises and risk controversies to question hidden or culturally implicit issues.

Second order analyses are performed in order to elaborate a coherent approach of industrial accidents with this newly built knowledge. This detailed knowledge cannot be established without a modelling effort within a critical framework relying on a contradictory debate between analysts and researchers upon the strength and the weaknesses or grey areas of the investigations of the accident cases [2].

Secondly, it is necessary to build a collective, *alive and dynamic memory* of accidents. The socio-political experiences of organizing the memory work on great historical events show that this requires institutional effort to avoid the loss of memory and the repetition of mistakes. This memory work is supported by the strength of the accident stories. This strategy is already used: *“The submarine Navy has a strong safety culture that emphasizes understanding and learning from past failures. NASA emphasizes safety as well, but training programs are not robust and methods of learning from past failures are informal. The Navy implements extensive safety training based on the Thresher and Scorpion accidents. NASA has not focused on any of its past accidents as a means of mentoring new engineers or those destined for management positions”* [5, p. 183] and some cases for training too [30].

After the pioneering work of several researchers to identify notions and concepts mentioned in §2.2, the capitalisation of recurring organisational factors influencing accident causation has been continued under the concept of *pathogenic organisational factors* (POFs). Some of them are for instance [24, 25, 26, 27]:

- Production pressures;
- Organisational complexity leading to obscurity and compartmentalization, excessive formalism or proceduralisation;
- Weaknesses of learning from experience;
- Complacency or deficiency of control authorities;
- Deficiency of communication or lack of quality of dialogue;
- …

To summarize and illustrate our proposals of a “new view” on learning from accidents (as Dekker [31] about human error), we compare it to a classic shared view of learning from incidents and accidents (table 1), especially its weaknesses.

TABLE 1. DIFFERENCES BETWEEN CLASSIC INCIDENT DATABASES (WEAKNESSES) AND (PROPOSALS OF) A *KNOWLEDGE AND CULTURE OF ACCIDENTS*

Concepts	A few features and weaknesses of present view of learning from incident/accident	A new view on learning from accidents
Learning objectives	Tendency to "symptoms botany" Tendency to capitalise an heterogeneous list of cause, of data/knowledge with poor context	Search for "grammar of signs" and syndromes Search for phenomenological structures relying on sociotechnical (MTO) interaction dynamics
Learning resources	Limits (competencies, budget) for analysing events internally	More resources due to the pressure of internal/ external control authorities and civil society
Depth of analysis of the sociotechnical system	Low depth of analysis of incident: direct technical causes and human errors Local view (technical system, operators) Chronology limited to last actions close to the event Normative approaches Global analysis on a specific industrial system/sector	Root causes (human, organisation, societal) including the deficiencies of vulnerability management Big picture, historical dimension and accident dynamic on longer duration, multiple causes, latent defects, incubation period Comprehensive approach Global analysis, inter-sectorial, regularities
Impact of corrective actions and generic interest	Focused on technical system within technical culture of the industrial sector, assumed best practices, corrective actions with limited impact, local (technical system, procedure, training)	Generic character of recommendations to adapt on the specific context (by comparison and/or mirror effect)

Knowledge transfers and memory work may ultimately influence worldview, beliefs, attitudes, values and hence safety culture. We consider that the "culture of accidents" partly differs from "safety culture" according to their main object of analysis (focusing on vulnerability phenomena rather than resilience-reliability phenomena). The culture of accidents should be integrated in and complement safety culture, and should favour a readjustment of priorities and levers. It would help to get some background knowledge to maintain *preoccupation with failure* [32].

4. HOW CAN WE USE THE LESSONS LEARNED FROM ACCIDENTS FOR NORMAL OPERATION?

After showing the reasons why we should better use the lessons from accidents, and some foundations for the capitalisation and transfer of the knowledge gained from accidents, this part aims at addressing the practical use of lessons in prevention of accidents, in normal operations. Several uses should be organised for operators in design and operations. Here we focus on the example of nuclear safety assessment which relies on organisational diagnosis.

4.1. Some use of lessons learned from accidents in safety assessment

4.1.1. The context of safety assessment in France

In France, regulatory control is carried by the regulatory authority (ASN, www.asn.fr) with the support of IRSN (www.irsn.fr) as the technical support organisation (TSO). Regulation compliance inspections are led by control authority inspectors with support from IRSN experts. Comprehensive safety assessments are performed by IRSN experts. Both approaches are complementary.

The goal of a safety assessment is to provide a robust and sounded basis for an expert judgment to aid a decision-maker. The decision-makers that will use the expert judgment are directly the control authority (ASN) and the operator. Both will use the findings, the criteria developed to argue them, the recommendations proposed to define regulatory requests or safety management provisions.

As requested by the ASN, IRSN conducts assessments of risk management performance of nuclear reactor operators (for energy production or research purposes) or from the nuclear fuel cycle (manufacturing, waste treatment). For those mobilising expertise in human and organisational factors (HOF), they can focus on some activities with safety stakes (e.g. operations in control room) during normal operations and on organisational provisions such as those found in safety management system, in operation, in maintenance and human resources management. They can be involved in event and emergency response analyses.

The use of lessons from industrial accidents and organisational approach was particularly implemented for two assessments of safety management performance by the French nuclear energy producer, Electricité de France (www.edf.fr). The first one focused on safety management in a competitiveness context (finalised in 2008) and the second one on safety and radiation protection management during maintenance activities in outages (finalised in 2013).

Such large-scale HOF assessments last between 2 to 3 years and involve 3 to 5 HOF part time experts to collect (by field observations, interviews) and analyse data and 2 supervisors. They involve also safety and radiation protection experts.

When conducting a safety assessment, one can distinguish two main phases of the use of the knowledge from accidents:

— *at the beginning* of the investigation, when framing it, with the main issues and key question to address, the object of the assessment, the lines of assessment,… At this stage, the lessons from accidents, the pathogenic organisational factors are useful to select the most important issues that an operator should manage safely and that should be investigated;

— *at the end* of the analysis and finally to support an expert judgment, when some situations or data of the case study on safety management performance require an interpretation, a comparison with some references cases and some criteria,… Indeed the criteria to support the expert judgment may have different origins, but the knowledge of accidents is useful for having a case in which a differential diagnosis (such as in the medical diagnosis [33]) is possible.

4.1.2. The implementation during two safety assessments

At the beginning of the investigation, to identify the scope, the driving key questions and the lines of assessment:

— For the 2008 assessment on "safety management in a competitiveness context" [34]:
  - *The key question:* it was upon the "priority given to safety" constraint after the privatisation of the public company Electricité de France. Indeed, the change of European regulatory context and of financial performance criteria may stress decision-making processes and management practices. In addition, knowing that the managerial and organisational contexts are submitted to frequent evolutions, is safety still meaningful to human operators? Do the organisational measures set up to manage safety (in order to counterbalance competitiveness oriented measures) allow EDF to maintain a "continuous improvement" of safety?
  - *The scope of the assessment:* it was decision-making processes, especially daily trade-offs potentially induced by high-level strategic decisions. Safety management was considered as the organisational framework for taking safety requirements into day-to-day decisions. Several analyses (based on observations, interviews, documents) involving the plants and central engineering departments were performed on various dimensions of decision-making processes: real-time constraints, learning from past decisions, management of internal control, management of the variations of representations regarding safety, collective decision-making, technical support for decision-making, change management,…
  - *The lessons of accidents used:* the ones particularly emphasised were mainly the production pressures with various patterns and effects visible in Paddington rail collision in 1999, Davis-Besse nuclear incident in

2002 and Columbia loss in 2003 [35]. However, other lessons from accidents were used to address the side effects of multiple changes as seen in several accidents (e.g. Columbia loss) and how safety improvement is achieved while several accidents have shown safety deterioration.

— For the 2013 assessment on "safety and radiation protection management during maintenance activities in outages" [36]:
  - *The key question:* It was much influenced by the effect of an organisational change (implementing Outage Control Center (OCC) to manage outage such as done in North America) and how change was conducted and managed. Does the new organisational model to manage outage enable the risk management in outage to become more efficient than in the past? Do the performance factors introduced by these new organisational provisions compensate past vulnerabilities? Are they creating new vulnerabilities? How was designed OCC and conducted the organisational change? How does it interact with other changes? What adjustments have been required?
  - *The scope of the assessment:* compared to the 2008 assessment, the scope was limited to outages, focusing again on decision-making processes and trade-offs, but all along the outage phases (preparation, execution, and learning) and at all levels of hierarchy (outage management and executants). The interface management between multiple actors, internal (with operations, maintenance, and outage project) and external (with subcontractors) was the bone line of assessment. It was enlarged to some safety management pillars such as management of change, learning from experience and human resource management. The safety analyses (based on observations, interviews, and documents) involved three reactor outages on three plants and the outage management re-engineering central department.
  - *The lessons of accidents used:* prior to the safety assessment and for all the assessment lines, specific analysis and synthesis of lessons (knowledge of accidents) were performed. The organisational complexity (internal and external with subcontractors) was at the origin of several accidents (Paddington rail collision in 1999, Columbia loss in 2003, Deepwater Horizon in 2010,…) [37]. Change management was also at the origin of several accidents (Columbia loss in 2003, Texas City refinery in 2005,…) [38]. Learning from experience failures are numerous [25, 39, 40]. And human resources weaknesses have been observed several times (Columbia loss in 2003, Texas City refinery in 2005,…) [26].

At *the end* of the analysis and finally to support an expert judgment, lessons from accidents were used in the two assessments:

— Some lack of anticipation but mostly of counter-measures early enough to counter the loss of expertise in outage workforce due to the retirement wave (the challenge was to face 30 to 50% of departures in five years). As a consequence, EDF has experienced a reduction in its experienced (more than five years within the job) workforce which could lead some departments to work with 30% to 50% of low experience (less than five years) employees [41]. Before Columbia loss, the NASA public servants and subcontractors' workforce reduction were severe (more than 40%) from 1993 to 2002 [5].
— Some excess in the will and rhythm of changes, during a difficult period with the multiple retirements of employees. OCC was not the only change impacting outage management. Several changes were part of a large scale program to increase the delivered performances: new maintenance methods (with AP913), new framework to manage subcontractors, new spare part management, human performance program implementation, harmonisation of procedures between plants, new IT tools. And the context was changing with a new safety regulation, ageing of equipment and workforce, and renewed research for competitiveness. The CAIB [5] entitled a chapter "*Turbulence in NASA hits the space shuttle program*". Indeed, Daniel S. Goldin, the NASA's Administrator, self-proclaimed that he was an "*agent of change*". In order to obtain "*administrative transformation*" of NASA, Goldin engineered "*not one or two policy changes, but a torrent of changes. This was not evolutionary change, but radical or discontinuous change*." "*His tenure at NASA was one of continuous turmoil, to which the Space Shuttle Program was not immune*".
— A trend to complexification of organisations by the multiplicity of roles at the interfaces which provide some redundancies but also generate side-effects such as barriers to communication and ultimately by-pass. Organisational complexity seems rooted in the NASA' history: *"NASA derives its organisational complexity from its origins as much as its widely varied missions"* ([5], p. 187). NASA never tried to "loosen" the complexity: *"the increased organisational complexity, transitioning authority structures, and ambiguous working relationships that defined the restructured Space Shuttle Program in the 1990s created turbulence that repeatedly influenced decisions made before and during STS-10710"* ([5], p. 121). These *"transformations rendered NASA's already problematic safety system simultaneously weaker and more complex"* ([5], p. 179).
— Some risks and cases of flawed decision-making due to inadequate roles confrontations, which can drift to reversing the burden of the proof posture

(highlighted in the decision to launch the space shuttle Challenger in 1986, [42] and in Columbia loss in 2003 [5]. The example is developed in [36]. Learning deficiencies were observed at various stages and echoes several accidents [39, 40]. The lack of competent resources to analyse properly successes and failures impeded the continuous improvement loop to operate. The lack of depth of analysis of events is a recurring weakness found in many lessons of accidents [25]. Some failures to implement the numerous corrective actions were found too.

4.2. Use of lessons from accidents in event analysis

Another task performed by IRSN analysts is to review the events analysis reported by operators to the safety authorities. Several meetings are done internally and with the operators and control authorities to determine if the findings are sufficient, if the root causes are addressed enough and if the recommendations to prevent the recurrence of similar events are adequate. Some trend analysis is performed from events databases (IRSN deals with approximately 1300 significant event reports per year coming from the French licensees). The objective is to recognise some common features, some differences of configurations, some common patterns, to capture emerging issues with generic potential, some symptoms, and some potential syndromes.

The main idea with the use of the knowledge of accidents, is to light some phenomenon observed in some events, by the ones observed in accidents, in order to give a preventive alert. With the medical metaphor in background, it means that like a doctor who knows the pathologies, the analysts may recognise (notice that this remains hard even for doctors!) some symptoms in some minor events.

To stimulate transverse and inter-organisational learning between nuclear operators (EDF, CEA, AREVA), some IRSN analysts perform the diagnosis and provide some reviews that contains explanations about the issues (pedagogic objective) and the alerts. They produce short reports that are sent regularly with a transverse analysis of several events on one issue to show that transfer of lessons is possible between nuclear operators (energy production, research, fuel cycle) and could improve the next safety assessment. In the document, if possible a lesson from an industrial accident is explained too, which shows the ultimate risk. In such a way, some culture of accident is expected to be enhanced.

In a case example, there were many events showing anomalies which were not treated and fixed for some time and finally were one of the causes of several events. It was diagnosed in those events that somehow a tolerance of persistent deviations had developed and was more or less accepted. It led the analyst to make the link with the concept of *normalisation of deviance* identified by Vaughan [42] in her analysis of the Challenger space shuttle accident in 1986 (about the boosters' o-ring damages despite contrary engineering specifications) and observed again in the

Columbia space shuttle loss (about foam losses, debris strikes on the orbiter despite contrary engineering specifications).

5. DISCUSSION AND PERSPECTIVES

5.1. The "royal road", "gift of failure" and normal operation approaches

The approach followed, which relies on the systematic study of accidents that aims at being pragmatic, may seem banal. In fact, it is a strong assumption that should be discussed.

Some researchers (especially from High Reliability Organisations [43, 44] and Resilience Engineering [45]) advocate studying normal operations (e.g. as they estimate that normal operations are not as studied as accidents; that accident reports are secondary documents compared to ethnographic studies of the daily life of organisations [46], seeking factors, practices, and "best ways", especially relevant to explain how success is obtained in adverse conditions, in order to grasp features of reliability and resilience.

Other researchers are advocating the study of events, failure and accidents (as they consider, not enough attention is given to those events compared to normal operations) in order to highlight features of vulnerability. Some researchers as Wilpert [47] considered that undesirable incidents and events, serious and disturbing as they may be, are a *gift of failure*. In short, events offer an opportunity to learn about safe and unsafe operations, generate productive conversations across engaged stakeholders, and bring about beneficial changes to technology, organisation, and mental models (understanding). Llory [2] argues that accident are the *royal road* (referring to Freud's metaphor about dreams being the royal road to access the unconscious) to access to real (mal) functioning of organisations.

The systematic and cumulative study of several incidents, accidents and crises, provides us an understanding and knowledge – that cannot be obtained in another way – of the dysfunctional dynamics and pathogenic factors that undermines organisation and the way these factors erode defence in-depth. Indeed, some hidden phenomena hardly evident in normal functioning may become more visible (especially those in the *dark side* of organisations [48]). Studies of accidents help to reverse the perspective: if the normal operations hardly show organisational pathologies, *accidents help to better understand the banality of the daily life in organisations*. This assumption echoes the medical analogy. To some extent, an implementation of this principle is illustrated in §4.

5.2. Potential impact of the proposals?

The proposals of new Knowledge and Culture of accidents aim at providing safety analysts, prevention actors and decision-makers, some background knowledge references. It should feed the referential and expert judgment black-box with some evidence cases, especially to sustain organisational diagnosis, risk analyses and to re-interrogate practices. Accident patterns' lessons should help to give some light on events' symptoms.

The impact of those proposals should be questioned. How useful can they be? Especially compared to other approaches, methods and tools? We believe that, to the contrary of sophisticated methods, these proposals are simple tools with high rhetoric potential. The lessons' transposition allows to set-up reasoning by analogy and enhance some differential diagnosis (by comparison and pattern recognition) like in medical diagnosis [33]. As observed during trainings of operational actors, the mirror effect of others' hard lessons through a complete story of accidents, shows that it is a simple tool for being reflexive about their own organisation. It helps identifying similarities, differences and some questions.

5.3. Theoretical and practical barriers to implementation of proposals

A common limit of the approach is summarised into the hindsight bias. It is common to hear [12, 42] that the two configurations of inquiry (before or after the event) are very different in terms of methods of investigation and finally in the exercise of judgment. In particular, after the event, the diagnosis would be greatly facilitated with the risk of being unable to avoid the pitfall of the famous hindsight bias. It also means that what is obvious to the analyst after the event could not have been for the actors before the event, because the signals of danger were blurred in the background noise of daily anomalies and deficiencies. As an example, Vaughan [42] concluded that some weak signals could not be understood before the accident because they were normalized in the NASA' culture.

We have found no strict dichotomy between lessons provided by normal operations studies and a posteriori investigations. Both knowledge are in fact potentially biased but for different reasons [23]. Normal operations studies' findings provide also valuable lessons but cannot guarantee that something is not missed, and while concluding on the reliability and resilience of an organisation, an accident waiting to happen could well be in progress. In practice, both knowledge are in fact quite complementary, but from a safety standpoint, the review of some historical cases was for us a prerequisite.

Other theoretical barriers do exist. As recalled, some analysts consider that an accident is a unique combination of causes and circumstances, and it would remain hard to transpose generic lessons as an identical accident would hardly recur. We oppose to this the recurrence of the root causes and of similar accidents. Scientific approaches often rely on the observation of recurring phenomenon.

One barrier is related to the time dimension. How could some knowledge of past accidents remain useful for prevention of future accidents that will probably be different, and that would occur on new sociotechnical systems or on systems that will have changed? We consider that the recurrence of patterns and root causes for more than a hundred of accidents, whatever the historical period for the last 50 years, the sectors, the companies, the regulators, the cultures is a lesson that cannot be ignored anymore. Some likely issues about organisational safety are pinpointed in advance thanks to the historical knowledge and experience base.

A last theoretical barrier would lie in the remaining techno-centred approaches of most designers and operators of the systems. They might continue to minimise and underestimate the transferability potential of lessons at organisational, inter-organisational, regulatory and cultural levels [9, 47]. Even for technical lessons (e.g. hydrogen recombiner), barriers to implement the lessons learned have been observed from Japanese nuclear industry.

These proposals may too suffer from barriers in practice such as the amount of human resources to capitalise this knowledge of accidents and to develop its use by the analysts in their organisational diagnosis. In addition, the transfer to the operational actors of some synthetic lessons of accidents, of extracts of knowledge's accidents, to sustain the culture of accidents and complete the safety culture, remains to be done, and its efficiency (appropriation, use) assessed in operation.

5.4. Some levers to overcome the barriers to implementation of the proposals

These barriers are defining challenges. Transferring the lessons learned from accidents to other actors requires going beyond the dissemination of a case that describe a particular (and often dramatic) story and therefore beyond the storytelling effect [49] and its emotional reactions that help though the memory of cases. It requires a transposition effort of the lessons to be learned in another's' context. The loss of context phenomenon requires a translation effort that can be performed in a particular process and with the support of a learning agency [50]. Several levels of transposition are required and although some collective work could be shared and performed at international and industrial sectors levels, the local use should be adapted to its historical context, culture and contingencies of the organisation targeted. The translator must help the user to avoid two pitfalls, the NIMBY (not in my backyard) phenomenon with a reaction considering that no lessons can be transposed to this specific case and its opposite, the belief that there is a full similarity between the case and the accident [9].

For the HOF community, a particular effort is to formalise doctrines and framework, and provide them to users. Some are generic across sectors; others should be adapted [10]. At least, knowledge and culture of accidents should help analysts to formalise and present synthetically the phenomenology, the patterns, and examples of organisational malfunctioning that threaten safety level and downplay safety management provisions. Experiences of training to HOF and learning from experience, shows that it is an adequate window to provide cases to be discussed.

The target remains to help getting a "full cultural readjustment" [11] and even a change of paradigm 30 years after Chernobyl and the safety culture concept.

The Diet report on Fukushima contains several key lessons which echoes to the previous lessons learned from several industrial accidents. Are we sure we will take full benefit from them?

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