

System Safety in Organizational Safety Decision Making

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The two cardinal aspects of safety are intrinsic safety and its demonstration. A key element of demonstrating system safety is the organizational structure that is best placed to ensure and demonstrate that high standards of safety are clearly in place for its products, processes and facilities. This is particularly important for high-consequence industries. Accomplishing this depends on a number of organizational integrated layers of scrutiny, ranging from the accumulation of arguments and evidence at the lower levels to final executive decision making. The latter holds final responsibility and accountability. Potential problems arise because products, processes and facilities are becoming more and more complex and the associated supporting data inordinately large. In turn, the organizational processes that enable top-level decision makers to make wise and informed decisions are themselves becoming more complex and difficult. This final stage requires clear and transparent communication.

Organizations have moved more towards the application of peer review to support final decision making but, nevertheless, one still expects the final decision-making layer to provide further independent scrutiny to enhance overall confidence in the process. This would represent a three-tier independent process — strength in depth. This is the subject of the paper.

Introduction

The specific contents of this paper represent the views of the author and not necessarily those of the Atomic Weapons Establishment in the United Kingdom; however, this organization operates broadly in this fashion.

Not only should a product, process or facility be intrinsically safe, but there must also be a process in place to demonstrate to the satisfaction of the user and regulators that it indeed does meet acceptable standards of safety. Both aspects are inextricably entwined. In fact, one might say that safety doesn't necessarily exist unless it can be shown to exist and, of course, the process of demonstration is not an exact science in itself. To combat this, there has been an evolution in the structured methodology by which this demonstration is best achieved. Its aim has been to gain confidence, through best practice and scrutiny, that all of the possible hazards are account-

ed for, eliminated or reduced to acceptable levels. We continue to strive for the ideal goal of perfection.

We are all familiar with the concept of system safety and the concepts of an overall approach to the safety of a complete physical system or operation. However, what is not so clear cut is the concept of the organizational safety system by which an organization sets in place a system for assuring itself that a product, process or facility is demonstrably safe and fit for purpose. In the U.K., organizations that are responsible for products, processes and facilities have a clear duty of care in respect to safety. They undertake the responsibility of safety assurance and are accountable if things go wrong. The assurance process is based on substantive arguments, supported by a foundation of evidence, to demonstrate that appropriate and acceptable standards of safety have been met. Ultimate responsibility and accountability for high-consequence "products" resides with the executive management of the organization, and this is not necessarily where the detailed technical knowledge, experience and skill sets reside. As products, processes and facilities become more complex, it is now customary to combat at least part of this difficulty with a complementary assurance process based on independent peer review to assure (or give more confidence to) decision makers that the correct (or an enhanced) level of scrutiny has been applied. The assurance process has the characteristic of independent challenge of the case put forward by the ensuring organization. One may well regard this as an application of the general principle of independent strength in depth, which is a well-established principle in technical and administrative safety. Despite this, top-level decision makers will be truly comfortable only if they are able to bring their own informed and independent contribution to the decision-making process. In this instance they will appear to represent the third element of independent scrutiny and strength in depth within the organization's system safety framework. To fully satisfy this role, they will need to establish a position such that they can truly apply this further element of true independence. In brief, such an organization will exhibit a framework based on three independent Lines of Defense for best practice in ensuring safety: Assurance, Authorization and Approval. This is akin to a fundamental technical safety requirement in the nuclear weapon design world.

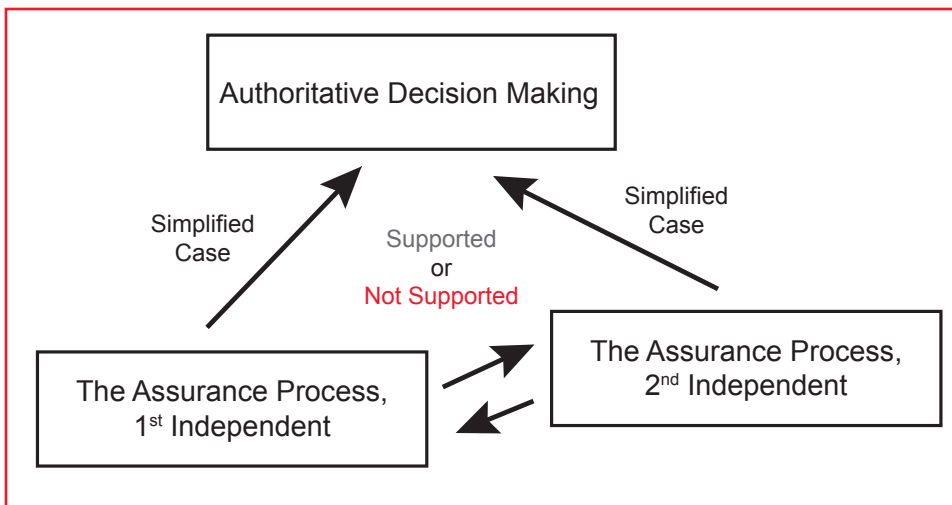


Figure 1 – An Organization's Independent Strength in Depth Approach.

In the complex world we now live in, the processes of ensurance and assurance have been widely tasked and exercised in meeting this challenge through developing the necessary tools and skill sets. Despite this representing a continuing and evolving challenge, by and large the processes have been and continue to be successful. The question remains as to whether in this complex world the Authoritative decision-making level in the Triad (Figure 1) really is in a position to provide a competent third level of independence or is it a case of now relying too heavily on the product from the first two processes. Is this an area that warrants further consideration? This aspect is covered later in the paper in terms of a simplified case or so-called “boiled down” case which contains all of the essential information necessary for the authoritative element, while avoiding long-winded nugatory complexity. Of course, there may well be unresolved conflict between the ensurance and assurance elements (not supported), which will need final resolution at the authoritative level.

Some Definitions

To explore this framework further, it is first worth setting down a particular set of definitions that are common in the U.K.

- **Ensurance:** The basic element of responsibility and accountability and the process tasked to demonstrate that the product, process or facility is fit for purpose (the case to demonstrate that the safety requirements are satisfied). The first leg.
- **Assurance:** An independent peer review process tasked to provide challenge to the ensurer's contentions and with the intention of providing further confidence in the substance of the ensurer's safety case (or alternatively identifying any serious flaws). The second leg.
- **Executive Authorization:** The organizational layer that finally authorizes a product, process or facility as fit for purpose and is accountable for that decision. The third leg.
- **Safety Case:** The basic elements of a safety case program are defined by the U.K.'s Ministry of Defence. *“It is a structured argument supported by evidence, which provides a comprehensive and compelling case that a system is safe to operate in a given scenario.”* This is a fully documented approach where clear

boundaries are set together with the standards to be met, the overall process adopted, and the supporting evidence and logic that demonstrate that the standards are met and that the attendant risks are broadly acceptable. One key element of the safety case approach is the element of *independent challenge and review*.

The Typical Modern-Day Scenario

Today, products, processes or facilities can be technically complex, incorporating various elements of engineering, science, technology, process engineering, manufacturing, human factors, ergonomics, etc. As such, the processes of both ensurance and assurance are in themselves complex. Team members must be well versed in the appropriate disciplines. In fact, the first requirement is that all of the relevant disciplines (especially those critical to safety) are covered and in the required depth, and that all stake holders are involved in an integrated process. Most people would agree that in addition to having the appropriate breadth of disciplines, it is essential to have a strong element of teamwork because, after all, the product of the individual processes of ensurance and assurance is very much an integrated one. The output from each team will be an agreed view (with perhaps a minority view if held strongly enough). In fact, not only is teamwork and effective communication important, but it is essential that these are established at the start of any program. At the end of the day, the success of the enterprise will depend on how the “safety burden” is best shared between the contributing components within each team. What needs to be avoided is a situation where some members take the position of ensur-

ing that “their element of responsibility” is protected at all cost and at the expense of others — a symptom common to silos. Ensuring that these requirements are met clearly rests on the shoulders of the team leaders.

What is not so clear at first sight is the need for teamwork between the ensurance and independent assurance processes. There appears to be a conflict in terms of maintaining the requirement of independence. However, on reflection, it is not really productive for the ensurance and assurance processes to plow on to the end of their respective programs in somewhat independent fashion. This would lead to “late time” major disagreements and major program disruption and repair. It would be more beneficial to ensure that any evolving differences are identified at an early stage of the program, where resolution can take place with less program disruption. Of course, both sides have separate (independent) responsibilities, but there is also a need to continually look for the best way forward. However, this must not take the form of the assurance process suggesting the best solution (but of course in the real word...) because this would be seen as undermining the fundamental requirement of independence (we are likely to love our own solution...). The approach will be based on the assurance process indicating what, in its judgment, is the nature of the “disagreement” so that the ensurance process can respond appropriately. This may result in either a counter challenge or in agreeing to look for a better solution that satisfies both parties. What are *not* helpful are entrenched positions. This is an area where realistic teamwork (and leadership) is necessary to avoid a stand-off that can become bitter, entrenched and detrimental to the program. This is not a case of the “weaker side” giving in to the other, but rather to one seeking a realistic way forward that both sides can support. Of course, resolution is not always possible and, in such circumstances, progress can be made only by decisions from an authorizing layer higher up in the management structure.

The above describes a general process known as Assertion, Challenge and Resolve.

Independence

The purpose of independence is clear from a managerial point of view: that the ensurance and assurance processes sit in different lines in the management struc-

ture so that there is no vested single management interest in having agreement or disagreement for the sake of personal and expediency reasons. However, achieving perfect independence in its most formal sense is more difficult than first appears in any real organization. It does, to some extent, depend on the nature and size of the organization and on the nature of its products, processes and facilities. The basic problem arises, however, because all organizations will be resource limited to some extent or another. The dilemma in setting up the most effective assurance team under such circumstances will be based on the best “compromise” between real capability and ideal independence. For example, those who are available and have the appropriate depth of knowledge, experience and capability may not be “ide-

ally” independent in the formal sense. Even if these people currently reside in a different management chain than that of the ensurance process, they nevertheless may have had previous connections with the product, process or facility under consideration and, therefore, there will be independence concerns. On the other hand, clearly independent assurers may be somewhat lacking in the required knowledge, experience and capability in the relevant disciplines. This is not an uncommon situation for many organizations and requires a clear strategy for team

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member choice in order to best optimize the overall goal of the assurance process. This responsibility rests mainly with the assurance team leader, who needs to satisfy him- or herself that the choice represents the optimal position and that the case for the choice meets higher authority approval. In principle, this provides the second independent element in the organization’s system safety managerial structure for strength in depth. Individual characteristics will play a part in the choice of assurance team membership in that they must have an open mind towards making fresh judgments on product, processes or facilities to which they may have made contributions in the past. In addition, there is a need to ensure that the members can operate in a cohesive team manner but, on the other hand, members should be able to argue their case forcibly, even if they find themselves in a minority position.

As noted previously, objectivity and independence of mind is a key requirement for the assurance team

member and will form part of his or her basic character. The team leader will need to be informed of previous member “attachments” to the product, process or facility, and to ensure that this past linkage will not become a barrier to fresh objective judgments by that individual. There is a clear need to forget past allegiances and be able to make fresh, objective scrutiny of the output from the ensurance process. The team leader needs to be assured that this is the case.

Combined Ensurance/Assurance Teamwork

It is clear, from what has been said previously, that the ensurance and assurance processes should form a close relationship from the start and, indeed, this relationship will need to extend to the authoritative layer to gain its agreement and successful integration. There must be agreement at an early stage on the operating strategy and content of the program. For example, to:

1. Agree on the definition, scope and purpose of the product, process or facility and the limitations of its application.
2. Agree on the phasing and time scale of the ensurance/assurance program, including the clear definition of each start and end point.
 - a. What and when will review items become available
 - i. Documents, designs, plans, videos
 - ii. Hardware
 - iii. Hands-on activity
 - iv. Trials
 - v. Supporting evidence
 - vi. Analysis
 - vii. Etc.
3. The safety standards that should be met
4. The necessary supporting evidence
5. The methodology of engagement during the whole independent review process
6. The process for resolution of disagreement

Ideally, this engagement will start during the concept phase of any product, process or facility, and will continue during the development and evolution of the chosen design, together with its testing, manufacture, implementation and performance demonstration. In some cases, this independent activity will cover the full cradle-to-grave lifecycle. A competent, successful, independent and timely assurance assessment during these various stages can only take place through well-planned and close, positive interaction between the two teams. At each stage, the assurance process will produce judgments on the adequacy of the ensurance proposals and provide

the basis for such judgments. Of course, such judgments can be either supportive or conflicting. For the conflict case sufficient assurance-based evidence should be provided in order for the two teams to find a realistic path to resolution. It is the ensuring element that bears responsibility for the safety of the product, process or facility. This process will continue to keep a record of disagreements, the basis on which they were resolved and those that could not be resolved and were passed to the authoritative level for sentencing together with the outcome. Even for those instances where both ensurance and assurance processes were in agreement, the reasoning and evidence for such agreement should also be recorded. This overall record will provide visibility of the fidelity of the overall process and will provide a key element in support of the authority’s decision-making process.

The final outcome of this ensurance/assurance joint program will be the final views provided to the decision-making authority on: whether the product, process or facility is or is not fit for purpose; agreement or not on the limits of safe usage, any outstanding caveats, and judgments and requirements for close out with respect to follow-up action plans. Both the ensurance contention and assurance responses then provide key support elements for the authoritative decision-making process.

Peer Review Team Member Attributes

It is instructive to review some of the skills, knowledge and characteristics required of team members who will carry out these more detailed processes. This applies generally and especially to the assurance element. These are exemplified in the summary in Table 1.

The Role of the Authoritative Formal Decision-Making Layer

As products, processes and facilities become more complicated in nature, together with the associated proliferation of associated data, the safety argument and the outputs from the ensurance and assurance processes also become more complex. In fact, there appears to be a strong appetite by these organizations, especially the ensurance element, to produce large complicated documentation that is not suitable for giving appropriate clear visibility and transparency to decision makers. There is a clear need here for the assurance process to play a key role in translating complexity into simplicity and clarity, without losing any of the essence of the final product. Any weakness in detailed technical knowledge will give rise to difficulties in authorized decision making unless this process of simplicity and clarity is successfully dealt with. If not, there will be an undermining of the requirement for the third layer of

Table 1 — A Summary of the Ideal Skills/Knowledge and Characteristics.

Skills		
1	Learn quickly	In related safety areas outside one's specific expertise
2	Advertise your capability	Encourage people to come for early advice.
3	See the wood from the trees	Real safety rather than trivial issues — not overly pedantic
4	Take concerns upwards	To have the courage, determination and skills to raise serious concerns upwards within the organization.
5	Articulation skills	The ability to make your point clearly to others, and particularly to senior decision makers, will be undermined without associated vocal and written articulation skills.
6	Context	One needs to understand the competing requirements faced by the company and judge solutions accordingly.
7	Regulation	To form sound working relationships with internal and external regulators.
Knowledge		
1	An expert	In at least one discipline/technical area
2	Standards, regulations and policy	To have a sound knowledge of national, international and company regulations, standards and company safety policy.
3	Keeping up to date	One can easily stand still and be left behind. It's never too late to have further training and to learn from courses, seminars, conferences, etc.
4	Others' failures	One of the most important processes in learning comes from the lessons gleaned from failures, not only from within but also from events in the external world. Keep abreast of these.
5	Mentoring	Enhanced safety must be a continuous function and, therefore, one of the roles of a system safety professional should be that of "bringing along" others in the discipline. One should never be so busy as to neglect this aspect.
Characteristics		
1	Determined	Not to concede a point if convinced one is right.
2	Diplomatic	Need to get positive engagement rather than negative confrontation.
3	To listen	Others will have something valuable to say — don't be too dogmatic.
4	To make oneself available	Safety is as much about people coming to you as about you going to them. Make yourself approachable.
5	Outward looking	Always be prepared to learn from others.
6	Admit when wrong	Accept that one is not always right, and better and more positive relationships are generated if you can accept it when you are wrong and others are right.
7	Prepare to discuss	Good safety is about good teamwork and communication, and there needs to be a culture of encouraging people to express opinions.
8	No blame — a just culture	The goal is to make things safer and part of this comes from an open culture that encourages reporting of errors, incidents and close calls rather than one of blame, which suppresses this activity.

independent scrutiny. It is now not uncommon to find that such a range of detailed technical knowledge is not present at all or not present to the degree necessary. Limitations may arise because the resident skills may be more biased toward the managerial rather than technical spectrum. Members of the third layer may not have a history of engagement for an extended period within the relevant technology areas. Of course, this is where the assurance process plays a key role in that it separately undertakes the detailed independent assessment and, as such, acts in direct support of the third layer. In this sense, it takes on the authority's detailed assessment burden and, as a result, allows the authority to concentrate on more top-level issues. Of course, these issues are not simply restricted to safety, but rather have to be balanced against other organizational imperatives, including how best to balance resources. Nevertheless, it is important that authority decision making enhances confidence based on the authority's ability to add a further independent element to the process. To do this, the authority will need a clear and independent understanding of the key issues and their implications. This is not simply a case of just assessing whether company processes have been followed and relying simply on the outcome of the assurance process. Of course, it is acknowledged that such company processes will have been put in place to aid in the decision-making process. However, a clear and independent understanding can only be gained if a complex safety case can be boiled down into a form with which the authority can work and provide its element of independent oversight. This "boiled down" version should clearly identify the applied principles, the core logical arguments, the principal supporting evidence and analysis and identify any significant remaining issues. This will include a relatively simple and transparent safety theme that clearly shows the approach strategy, the applied principles and the principal evidential elements. Experience shows that this is not a simple task, but it falls upon the assurance and assurance processes not only to cover all of the subject areas in detail, but also to provide such a "boiled down" version.

Transformation of the Detailed Assurance and Assurance Process to the Boiled Down Case

As noted previously, safety cases can be very complex in detail (and require detailed peer review), but in addition, they also should clearly identify the required standards, the principal hazards, the principal safety arguments and their implementation, the overall methodology and the supporting evidence which all support

the overall case (the boiled-down version) in order to aid organizational top-level independent decision making. This top-level review should not become simply a check of whether company processes have been correctly followed, what level of resource has been applied or have become a box-ticking exercise.

The ability to carry out such top-level review would benefit from the following aspects in relation to the boiled-down version, including:

- A clear beginning and end
- Identification of all the principal potential hazardous outcomes
- The safety standards and associated risk levels
 - Basic Safety LevelU.K.
 - Basic Safety Objective.....U.K.
- Identification of the safety principles and their application
- A clear and transparent safety-based strategy and theme
- The principal evidence and analysis that support the case.
- The key contents of a safety management strategy
- Application of strength in depth and redundancy where required
- Adherence to "accepted best practice"
- Application of the fail-safe principle where appropriate
- A top-level ALARP (As Low As Reasonably Practicable) case for risk acceptance
- Problems encountered and their resolution
- Restrictions on the acceptable application for the product, process or facility identified
- Contingency plans for hazards mitigation

The case should not become an internal exercise in itself, but should be continually focused on real safety.

The key here is clarity, simplicity and transparency with a determined approach to resist the temptation for nugatory detail, complexity and size. It is acknowledged that this is by no means a simple task and will include iterations between the ensurers, assurance and the needs of the decision-making authority. It has been suggested that safety cases should adhere to the following six principles [Ref 1]:

- Succinct
- Home-grown
- Accessible
- Proportionate
- Easy to understand
- Document-light

Dangers that Can Undermine the Overall Process

Of course, there are many dangers that lurk in the sense that they can undermine the intent of the three-stage process described previously. Many of these have been listed before, and there is an extensive reading list in the Haddon-Cave report following the Nimrod tragedy [Ref 1].

The following list gives a flavor of these potential pitfalls. They can be broadly listed under organizational and operational headings.

Organizational

- An inadequate or poorly executed organizational safety culture and its hierarchical position
 - Box-ticking culture
 - Unjust culture
 - Lack of independence
 - Discouragement of openness
 - Poor commitment and leadership
 - Subservience to program and commercial imperatives
- Optimistic view of past safety-related history, both internal and external
 - “Couldn’t happen here!”
 - Lack of corporate memory
 - Loss of corporate experience and knowledge
 - Be careful who you get rid of and why!
 - Commercial versus technical
- Project, budgets, costs and time scale constraints
 - Relegation of safety importance
- Endless reorganization
 - Lack of stability
 - Lack of continuity
- Shift from “functional” to “project-oriented” organization hierarchy
 - The danger of ill informed decisions
- Normalization of deviance
 - Danger of falling foul of the Normal Accident Cycle [Ref 2]
- Technical and organizational complexity
 - Lack of simplicity and transparency
 - Many interfaces
 - Poor communication and integration
- Absence of periodic review
- Reactive, rather than proactive, culture
- Not subscribing to eternal vigilance

Operational

- Trying to do too much with too little
 - Realism
- Lack of the appropriate range of technical disciplines and experience — depth and scope

- Too much compartmentalization, too many interfaces and loss of effective communication
- Bureaucracy and process trumps thoroughness and reason
- Dangers of outsourcing to contractors
 - Maintaining intelligent customer status
 - How do we assure this?
- Lack of regulation oversight
- Lack of coherence in databases
- Process through PowerPoint rather than through fully authorized and accountable documentation
- Danger of relying too much on process and procedure, as opposed to technical quality and people
- Poor leadership
- Don’t just read about it — see it for real
- Lack of familiarity with literature on accident theories [Ref 2]
 - High reliability
 - Normal
- Not diving down to root cause
- Beware of the closed-mind syndrome!
 - A flexible culture
 - Don’t forget the reality of human error
- Not expecting the unexpected (“What if?”)
 - A questioning approach
- Lack of clear and accepted accountability

The safety case is not the objective in itself — the objective of the safety case is safety!

In addition, it is instructive to have regard to some of Donald Keough’s edicts on reasons for business failure, [Ref 3]:

- Be inflexible
- Isolate yourself (i.e., work in silos)
- Assume infallibility
- Play close to the game line
- Don’t take time to think
- Put faith in [external] consultants
- Love bureaucracy
- Send mixed messages
- Be afraid of the future

Summary

One might say that safety doesn’t necessarily exist unless it can be *shown* to exist and, of course, the process of demonstration is not an exact science in itself — how do you prove a negative? To combat this, there has been an evolution in the structured methodology by which this demonstration is best achieved.

This paper covers the subject of the need for a safety organizational structure that itself has the char-

acteristics of what is more familiar in the conventional technical sense as “system safety.” This structure needs to deal with the current complex world of safety concepts, design, evidence, implementation and final decision making, and is of particular importance for high-consequence industries. It is a safety system in its own right. As such, it needs to operate in a closely coupled integrated manner to avoid all the traditional problems associated with interfaces — e.g., poor/ambiguous communication, “falling between the cracks,” different agendas, different sub-cultures, etc. A particularly effective structure, and one that is gaining ground, can be built up from essentially three independent layers and, as such, demonstrates the traditional advantages of strength in depth. Such a framework would appear to be well configured to meet the safety challenges of today’s world of complexity and realistic constraints on resources. The roles of the contributing layers are significantly different, apart from the common goal of providing an optimized process and structure for achieving and demonstrating overall system safety. The ensurance process essentially provides all of the detailed information, evidence, logic and building blocks necessary for demonstrating the case for safety. It will be very much bound up with real-world complexity and large quantities of data and, as such, will be resource intensive. The assurance process has a somewhat different objective, in that its role is that of carrying out independent critical scrutiny and challenge of the output from the ensurance process. To do this, it has to dip into the details of the complex ensurance output and associated supporting material, but do so in a proportionate manner. Its role is not to check on all of the fine detail in the ensurance process, but to assure itself that there are no significant doubts or areas left untouched. Of course, it shoulders the responsibility for deciding what it regards as proportionate and for being able to defend that position and in addition make a convincing case for independence. For

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these reasons, it will be less resource intensive than the ensurance process. Finally, it has to produce a clear case with supporting evidence as to why it supports or fails to support the ensurance output. The joint goal of ensurance and assurance is to produce a simple, evidential and transparent case to demonstrate why the product, process or facility is supportable on safety grounds. This case will need to be easily understood at the decision-making level and it should clearly identify: the principal issues and concerns covered during the assessments, their resolution, the evidential basis, any continuing issues and caveats which would require further resolution and the

suggested way forward. However, it is essential that the decision-making layer clearly contributes its own element of independent judgment. *It should not be a simple acceptance of the outputs from the ensurance and assurance processes.*

About the Author

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