



STANDARDS RESEARCH

# Contrasts in Safety Management: Safety-Critical Industries vs. Healthcare

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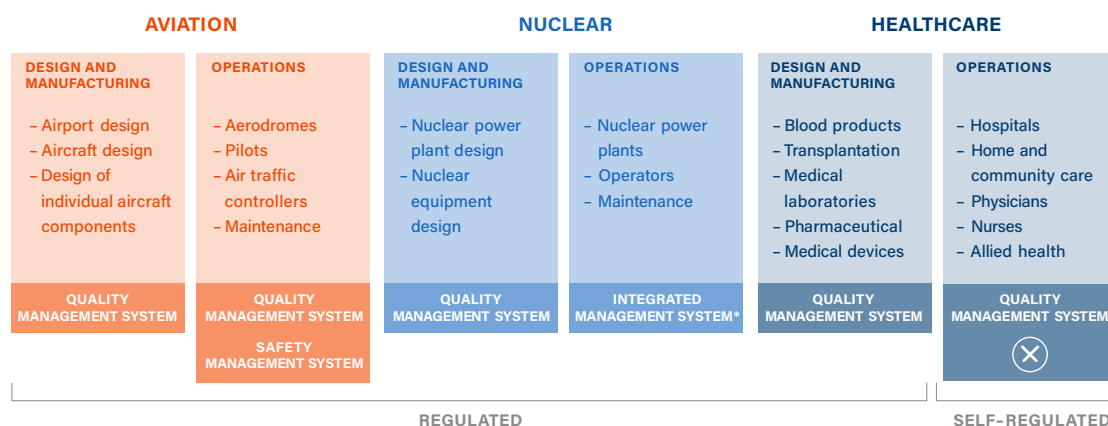
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# Executive Summary

Aviation, nuclear energy, and healthcare can each be characterized as safety-critical industries, defined as where “safety is of paramount importance and where the consequences of failure or malfunction may lead to injury or loss of life.” However, healthcare has a higher number of preventable serious adverse events in comparison to aviation and nuclear energy. For example, in 2015, the total number of airline passengers carried on scheduled service was 3.5 billion with 92 accidents and 474 fatalities. In contrast, of the 421 million people hospitalized in the world annually, approximately 42.7 million experience an adverse event. In Canada alone, more than 138,000 acute care hospitalizations in 2014–2015 involved occurrences of harm. Direct comparisons are difficult to make given the circumstance and invasive aspect of healthcare delivery, but it suggests that tactics used in aviation and nuclear energy that allow for a higher degree of consistency in the delivery of a safety-critical service could be adopted in healthcare that could result in improved outcomes.

To date, the tactics from aviation and nuclear energy that have been implemented in healthcare delivery service have included the use of checklists for critical tasks, crew resource management for improved team communication, and the experimental use of “black box” recorders in the operating theatre. However, many of the safety practices of aviation and nuclear energy for ensuring safety are largely unknown or unused in healthcare. A review of regulations and standards literature in aviation and nuclear energy indicates that there are explicit regulatory requirements to implement *safety management systems* and *quality management systems*, or a combined *integrated management system* at the organizational level. These industries have standardized processes to execute high-risk tasks and perform operations and have a high degree of reliability built into their systems that is often unmatched in healthcare delivery. As part of the management systems, aviation and nuclear energy utilize control tools such as *process control*, *change control*, and safety assurance practices such as *proactive hazard identification*, *risk assessment*, and *mitigation effectiveness verification* to ensure consistent and safe operations. Application of safety and quality management systems to the extent implemented in aviation and nuclear energy has not been fully investigated or applied in healthcare practice.

## Contrasts in Safety Management: Safety-Critical Industries vs. Healthcare



\*Nuclear Energy has an integrated management system which embraces health, safety, security, environment and quality (HSSE&Q) so that changes are managed so as to achieve continuous improvement in all the subject areas and the interfaces with other compliance regimes.

These tactics are not entirely unknown in healthcare, although they are typically applied in the support of care, rather than explicitly in its delivery. Industries that serve the operations of hospitals and clinics, such as pharmaceutical manufacturing, medical device development and manufacturing, and support services such as blood components, organ transplantation, and medical laboratories explicitly have the use of control process standards in place. Lack of control processes may be contributing to the ad hoc nature of healthcare delivery processes, and may result in poor quality and preventable adverse events.

Additionally, aviation and nuclear energy identify worker fatigue as a major safety risk and are required to have systems and processes in place to manage fatigue, including explicit limits on consecutive work hours. Healthcare provider fatigue and its impact on patient safety has been the subject of research, and guidelines do exist. However, there are few examples of enforced fatigue management standards in general, and limits to clinician work hours are often left to an individual's own judgement.

Through interviews with healthcare stakeholders and subject-matter experts, it was found that implementation of these aspects of safety management systems is not consistently applied in the delivery of care and is not as comprehensive as in aviation and nuclear energy. The following themes were derived through analysis of the interviews:

1. Lack of explicit **safety management** in healthcare delivery
2. Lack of **control processes** to ensure uniform, consistent practice in healthcare delivery
3. Lack of proactive **risk management** and **mitigation effectiveness verification** in healthcare delivery
4. Lack of **fatigue management** practices in healthcare delivery
5. Lack of **reliability** of safety-critical tasks in healthcare delivery

The review of regulations, standards, and guidelines in aviation, nuclear energy, and healthcare service delivery showed that all three industries require the implementation of a quality management system (QMS). However, only aviation and nuclear energy have explicit requirements, stated in regulations and/or standards, for implementation of a safety management system (SMS).

There are many challenges to address these gaps in process, policy, and regulation in healthcare delivery. There are hundreds of discrete healthcare services delivered in any system that would require greater rigour in process design to enable comparisons to aviation and nuclear energy practices. Areas of care delivery that are most amenable to a comprehensive safety management system with the identified themes should be identified as a high priority in any implementation.

Given the safety-critical nature of healthcare delivery and the lack of explicit safety management systems, it is recommended that a standard be developed to address the noted safety deficiencies in healthcare organizations and the regulation of practitioners. A safety management system standard for healthcare delivery would address the gaps in rigour that are currently present in practice at the individual and organizational level.





*"...there remains much more to do if healthcare is to improve to levels comparable to other safety-critical industries."*

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## 1 Introduction

The high incidence of morbidity and mortality in the healthcare sector due to preventable adverse events continues to stymie safety experts (Bates & Singh, 2018; Makary & Daniel, 2016). Although there is an ongoing debate as to the number of deaths directly attributable to safety issues in healthcare, there is no argument that the number continues to be too high, and the progress, if any, has been difficult to measure (James, 2017; Makary & Daniel, 2016; Shojania & Dixon-Woods, 2017a, 2017b).

After 20 years of effort since the landmark Institute of Medicine study on patient safety (Kohn et al., 2000), there remains much more to do if healthcare is to improve to levels comparable to other safety-critical industries. A safety-critical industry is defined as "an industry in which safety is of paramount importance and where the consequences of failure or malfunction may lead to injury or loss of life" (Amalberti, Auroy, Berwick, & Barach, 2005; Saunders, Gale, & Sherry, 2013).

Aviation is a safety-critical industry with a notable record of success. In 2015, the total number of passengers carried on scheduled service flights was 3.5 billion with 92 accidents and 474 fatalities (International Civil Aviation Organization, 2017). Contrast this with healthcare, where 421 million people are hospitalized in the world annually with approximately 42.7 million adverse events during

these hospitalizations (World Health Organization, 2018). In Canada alone, more than 138,000 acute care hospitalizations in 2014–2015 involved occurrences of harm (Canadian Patient Safety Institute & Canadian Institute for Health Information, 2016).

A number of learnings from aviation and nuclear energy safety practices have been applied to healthcare. These include;

- the use of checklists (Gawande, 2009; Haynes et al., 2009; Urbach, Govindarajan, Saskin, Wilton, & Baxter, 2014),
- crew resource management (Gross et al., 2019; Wakeman & Langham, 2018), and
- most recently, the analogous use of the "black box" flight recorder in the operating room setting (Bowermaster et al., 2015; Jung, Jüni, Lebovic, & Grantcharov, 2018).

Although these tactics have shown promise, and have even shown a degree of adoption, they are not an exhaustive use of the safety practices of the aviation and nuclear energy industries.

To this end, the purpose of this research was to compare and contrast quality and safety management standards and practices in aviation, nuclear energy, and healthcare.



AVIATION



NUCLEAR  
ENERGY



HEALTHCARE

It was hypothesized that beyond the already implemented patient safety practices in healthcare, there remain other quality and safety system learnings that can be adopted from these other safety-critical industries.

A scoping literature review was conducted on quality and safety management standards and practices applicable to aviation, nuclear energy, healthcare support services, and healthcare delivery services. In order to validate that the available standards were used in practice in these industries, interviews with subject-matter experts in all three industries were undertaken. Interviews were recorded, transcribed, and analyzed to identify themes on implemented standards, systems, and best practices in aviation and nuclear energy — in contrast to healthcare delivery.

## 2 Methodology

### 2.1 Scoping Review

The international standards, regulations, and guidelines applicable to aviation, nuclear energy, and healthcare were identified and reviewed.

The International Civil Aviation Organization (ICAO) develops aviation operations, safety, and maintenance standards, and recommended practices (International Civil Aviation Organisation, 2005, 2013; International Civil Aviation Organization, 2008, 2009, 2010a, 2010b, 2013) that are adopted by member states (193 countries). Canada and the United States are part of the member states of the ICAO and have established legislation to appoint a regulatory body to oversee civil aviation operations. The U.S. Federal Aviation Authority (FAA) (Office of the Federal Register, 2019) and Canadian Aviation Regulations (CARs) (Government of Canada, 2019) were reviewed to understand aviation safety,

quality, and operational requirements enforced by American (FAA) and Canadian regulators (Transport Canada). Fatigue management standards and guidelines were also reviewed to understand how aviation manages worker fatigue (International Air Transport Association, International Civil Aviation Organization, International Federation of Airline Pilots' Association, 2015; International Civil Aviation Organization, 2016; Transport Canada, 2007a, 2007b, 2007c, 2007d).

Similarly, nuclear energy also has an appointed international organization, the International Atomic Energy Agency (IAEA), which ensures peaceful and safe use of nuclear materials and governs the use of nuclear energy. IAEA has 171 member states and requires each of them to establish legislation and a regulatory body to oversee nuclear operations and use (International Atomic Energy Agency, 2016a, 2019). The Canadian Nuclear Safety Commission (CNSC) and U.S. Regulatory Commission (NRC) are the regulatory bodies that regulate nuclear operations in Canada and the United States. Nuclear energy regulations and standards by CNSC, IAEA, NRC, and CSA Group (Canadian Standards Association) were also reviewed (Canadian Nuclear Safety Commission, 2017, 2018; Canadian Standards Association, 2012a, 2017b; International Atomic Energy Agency, 2006, 2008, 2009, 2016b; U.S. Nuclear Regulatory Commission, n.d.).

Canadian regulations, international standards, and international guidelines related to healthcare support services and healthcare delivery were identified and reviewed (Canadian Standards Association, 2012b, 2017a, 2018; Council of Europe, 2004; European Committee for Standardization, 2017; Government of Canada, 2015a, 2015b; Health Canada, 2012, 2014; International Standard Organization, 2012; Standards Council of Canada & Canadian Standards Association, 2016; WHO Expert Committee on Biological Standardization, 2017; World Health Organization (WHO), 2011). Healthcare support services can be defined as non-clinical processes, such as blood and blood components processing facilities, organ transplantation processes and transport, laboratory operations, and medical device design.



Comparisons and contrasts were made between standards with respect to safety and quality management system elements such as process control, change control (related to quality) or management of change (related to safety), risk management, fatigue management, and reliability.

2.2 Stakeholder Identification

To understand the extent to which standards are implemented in aviation, nuclear energy, and healthcare, subject matter experts (SMEs) from all three industries were identified and interviewed. Semi-structured interviews were conducted with ten SMEs from September 2018 to November 2018. Healthcare stakeholders were identified based on their knowledge and understanding of patient safety initiatives and challenges and their experience with safety and quality standards. Aviation and nuclear energy stakeholders were selected based on their knowledge of management systems and experience within the areas of safety and quality management and operations. The backgrounds and associations of these SMEs are presented in Table 1.

For the purpose of these interviews, two interview scripts were prepared. The questions for the aviation and nuclear energy industries were framed around application of process control, change control, safety risk management, fatigue management, and reliability. The purpose of the line of questioning was to verify the

elements that were in the standards and regulations and the extent to which these are applied in actual practice, and to identify challenges that were experienced with implementation of these practices.

The healthcare interview script was framed around the same safety and quality processes listed above. However, with these interviews, the main goal was to identify areas of healthcare delivery that have these practices in place or would benefit from application of such principles. Additionally, the study aimed to identify the benefits and challenges of implementation of the previously identified quality and safety processes. Thematic analysis was used as a technique to identify themes and develop recommendations for further action. The following themes were derived from analysis of the interview transcriptions:

- Lack of explicit safety management in healthcare delivery
- Lack of control processes to ensure uniform, consistent practice in healthcare delivery
- Lack of proactive risk management and mitigation effectiveness verification in healthcare delivery
- Lack of fatigue management practices in healthcare delivery
- Lack of reliability of safety-critical tasks in healthcare delivery

Table 1 - Stakeholders

AVIATION	NUCLEAR ENERGY	HEALTHCARE DELIVERY
ALBERTA	ONTARIO	ONTARIO
Edmonton Regional Airport Authority	SNC-Lavalin Inc. (Engineering Consulting Company)	University Health Network <ul style="list-style-type: none"><li>▪ Radiation Medicine</li><li>▪ Surgery</li><li>▪ Risk Management</li></ul>
West Jet Canada	Independent Nuclear Engineering Consultant	Sunnybrook Health Sciences Centre <ul style="list-style-type: none"><li>▪ Radiation Medicine</li><li>▪ Rehabilitation</li></ul>
		The Hospital for Sick Children <ul style="list-style-type: none"><li>▪ Patient Safety</li></ul>



*"In contrast to aviation and nuclear energy industries, there is little to suggest that there is the same rigour or approach towards a systematic management system for quality and safety in healthcare delivery."*

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## 3 Findings and Discussion

### 3.1 Safety Management

*Theme: Lack of Explicit Safety Management in Healthcare Delivery*

#### 3.1.1 Regulations, Standards, and Guidelines

Based on the literature review of aviation and nuclear energy regulations and standards, it was found that aviation and nuclear energy organizations are required to implement both a safety management system and a quality management system, or an integrated management system which is the case in nuclear energy (Canadian Standards Association, 2012a; Government of Canada, 2019; International Atomic Energy Agency, 2006; International Civil Aviation Organisation, 2013; International Civil Aviation Organization, 2013; Lee & Kim, 2015).

A **management system** is defined as "the framework of processes, procedures, and practices used to ensure that an organization can fulfill all tasks required to achieve its objectives safely and consistently" (Canadian Nuclear Safety Commission, 2018). Safety in aviation is defined as "the state in which risks associated with aviation activities, related to, or in direct support of the operation of aircraft, are reduced and controlled to an acceptable level." A **safety management system** (SMS) is "a systematic approach to managing safety, including the necessary organizational structure, accountabilities, policies and procedures". Quality is defined as the

"degree to which a set of inherent characteristics of an object fulfills requirements" (Canadian Standards Association, 2016). A **quality management system** (QMS) is "a set of interrelated or interacting elements of an organization to establish quality policies, quality objectives, and processes to achieve those objectives" (Canadian Standards Association, 2016).

Components of SMS and QMS may seem similar, with some elements in common, but are viewed as complementary. Common elements are audits, performance monitoring, and continuous improvement of the management system (Civil Aviation Authority of New Zealand, 2012). However, an SMS is inherently risk-based and differs from a QMS in this manner (Civil Aviation Authority of New Zealand, 2012). The purpose of an SMS is to identify safety-related hazards, assess the associated risk, and implement effective risk mitigations to ensure operations within an acceptable safety envelope (International Civil Aviation Organization, 2013; Lee & Kim, 2015). In contrast, the QMS is concerned with the quality of a product or a service and customer satisfaction, and focuses on the consistent delivery of products and services that meet relevant specifications (International Civil Aviation Organization, 2013; Lee & Kim, 2015).

The review of regulations, standards, and guidelines in aviation, nuclear energy, and healthcare service delivery showed that all three industries require the implementation of a QMS. However, **only aviation and nuclear energy have explicit requirements for implementation of a SMS.**

Figure 1 - Elements of Standardized Safety Management Systems (SMS) and Quality Management Systems (QMS) in Safety-Critical Industries



An aviation framework for a SMS includes the four components and twelve elements listed below:

Figure 2 - Components of Aviation Safety Management System From ICAO Annex 19 Safety Management System [21]

SAFETY MANAGEMENT SYSTEM (SMS)			
SAFETY POLICY AND OBJECTIVE	SAFETY RISK MANAGEMENT	SAFETY ASSURANCE	SAFETY PROMOTION
● Management commitment and responsibility	● Hazard identification	● Safety performance monitoring and measurement	● Training and education
● Safety accountabilities	● Safety risk assessment and mitigation	● The management of change	● Safety communication
● Appointment of key safety personnel		● Continuous improvement of the SMS	
● Coordination of emergency response planning			
● SMS documentation			

A nuclear energy safety management system is expected to include components such as the use of controlled documents, processes, and practices to carry out tasks, change control, hazard identification, risk assessment and mitigation, and mitigation effectiveness verification (Canadian Nuclear Safety Commission, 2018; Canadian Standards Association, 2012a).

Review of regulations, standards, and guidelines for some **healthcare support services** showed that there

are references within these documents to certain components of a quality management system, but they lack the requirements for a safety management system (Canadian Standards Association, 2012b, 2017a; Council of Europe, 2004; Government of Canada, 2015a, 2015b; Health Canada, 2012, 2014; International Standard Organization, 2012; Standards Council of Canada & Canadian Standards Association, 2016; WHO Expert Committee on Biological Standardization, 2017; World Health Organization (WHO), 2011).

Canada's blood products regulations, guidelines, and the CSA Z902, Blood and Blood Component standard require **blood product establishments** to have a quality management system independent of other functional units (Government of Canada, 2015b; Health Canada, 2014; Standards Council of Canada & Canadian Standards Association, 2016; WHO Expert Committee on Biological Standardization, 2017).

As per Canadian regulations, the CSA Z900 series standards, and guidelines on **cell, tissue, and organ transplantation**, establishments are recommended to have a quality assurance system in place (Canadian Standards Association, 2017a; Council of Europe, 2004; Government of Canada, 2015a; Health Canada, 2012).

The ISO **medical laboratories** standard, World Health Organization (WHO) guideline, and the standard by CSA list several quality management system components recommended for medical laboratories (Canadian Standards Association, 2012b; International Standard Organization, 2012; World Health Organization (WHO), 2011).

Only two **healthcare delivery** standards were identified for quality and safety; for the perioperative environment by CSA, and the European Standard for clinical processes (based on ISO 9001) (Canadian Standards Association, 2018; European Committee for Standardization, 2017). Both these standards lack the noted safety management system principles and components described above, and are solely focused on quality and quality management.

There were no explicit requirements specified within healthcare support services or healthcare delivery regulations, standards, or best practices for implementation of a safety management system.

### 3.1.2 In Practice

From interviews with aviation and nuclear energy subject matter experts (SMEs), it was found that these industries use a safety management system approach through established standards and have clearly defined safety requirements and accountabilities.

Aviation has in place a safety management system standard which places the responsibility for implementation and maintenance of a SMS on individual aviation organizations. Under the safety management system there are explicit requirements that aviation organizations need to satisfy in order for them to be granted or to be able to maintain their license for operations.

Similarly, nuclear energy SMEs identified the CSA N286 standard, *Management system requirements for nuclear facilities* as the standard used for quality and safety management in the nuclear industry. Design control, change control, process control, procurement planning, testing, and validation are elements of the management system standards that are implemented and strictly followed in the nuclear industry. The nuclear energy industry must also meet certain license criteria and requirements to be able to continue operations.

Both the aviation and nuclear energy industries are required to define levels of accountability, responsibility, authority, and acceptable and unacceptable behaviour. The safety management requirements in both industries are applicable to all levels of the organization from management to contractors.

Healthcare delivery SMEs identified that there are certain elements of safety management, such as incident investigations, root-cause analysis, and corrective and preventive actions that are implemented in the hospital setting. However, these processes are implemented outside of a formal safety management system and therefore are not applied consistently or systematically.

In contrast to aviation and nuclear energy industries, there was little to suggest throughout the interviews that there is the same rigour or approach towards a systematic management system for quality and safety in healthcare delivery. In contrast to these other safety-critical industries, healthcare was characterized as self-regulated and interpreted as an independent practice where care is often delivered with a high degree of personal, professional autonomy.

### 3.2 Control Processes

*Theme: Lack of control processes to ensure uniform, consistent practice in healthcare delivery*

#### 3.2.1 Regulations, Standards, and Guidelines

##### — 3.2.1.1 Process Control

**Process control** is defined as “the management of processes and procedures that affect the quality of products and services, with the goal of ensuring that processes and procedures are performed consistently and as they were intended to be performed in order to produce predictable output” (Health Canada, 2014). Process control may be achieved through (1) standard operating procedures and the processes of (2) verification and (3) validation.

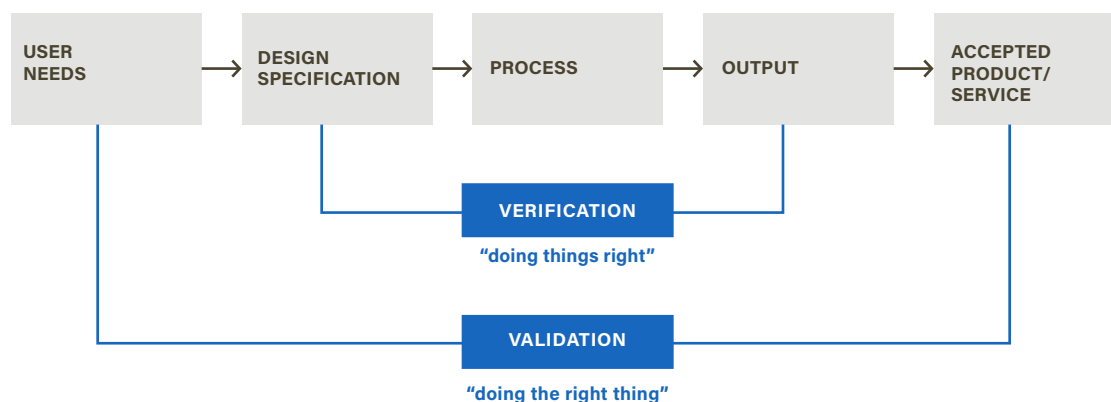
**Verification** is defined as “a process through which new development is evaluated against its design specification” (European Committee for Standardization, 2017).

**Validation** is defined as “a process through which a new development is tested under controlled conditions to see if it meets the performance requirements” (European Committee for Standardization, 2017).

In aviation standards, there are requirements for certain processes, such as emergency operations, to be designed, planned, and tested to verify that the emergency response plan is adequate and effective (International Civil Aviation Organization, 2009). This may be accomplished by conducting periodic emergency drill exercises where the designed plan is executed, and areas of improvement are identified.

Similarly, nuclear energy standards specify that process, design requirements, and verification should be defined and planned to ensure that work is managed appropriately (Canadian Standards Association, 2012a). This includes defining and assigning resources to the tasks, defining critical characteristics of the work that have to be verified, and identifying the acceptance criteria of the final deliverables. To ensure that processes are controlled, the manner in which the work is conducted must be through controlled documents, software, processes, and practices. The work needs to be independently verified by workers who did not perform the work to confirm that it meets acceptance criteria and established requirements (Canadian Standards Association, 2012a).

**Figure 3 – Verification and Validation in Process Control**







*“Management of Change is a best practice used to ensure that safety, health, and environmental risks are controlled when a company that is subjected to major accident hazards makes changes in their facilities, documentation, personnel, or operations.”*

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Process control requirements are specified in some healthcare support services standards and regulations (Canadian Standards Association, 2012b; Government of Canada, 2015b; Health Canada, 2014; International Standard Organization, 2012; Standards Council of Canada & Canadian Standards Association, 2016; WHO Expert Committee on Biological Standardization, 2017; World Health Organization (WHO), 2011). Examples of such requirements are validated operating procedures for activities that affect safety, efficacy, and quality of blood processing establishments, and validated processes and equipment for medical laboratories (Canadian Standards Association, 2012b; Government of Canada, 2015b; Health Canada, 2014; International Standard Organization, 2012; Standards Council of Canada & Canadian Standards Association, 2016; WHO Expert Committee on Biological Standardization, 2017; World Health Organization (WHO), 2011).

The standards for healthcare delivery include requirements for healthcare organizations to establish standard operating procedures (SOPs) and to describe the services provided by the healthcare organization (Canadian Standards Association, 2018; European Committee for Standardization, 2017). A quality management standard for healthcare (DIN EN 15224), primarily based on the ISO 9001 standard, also has requirements for systematically defining and managing clinical processes, their interdependencies, and interactions (European Committee for Standardization, 2017). This quality management standard is the

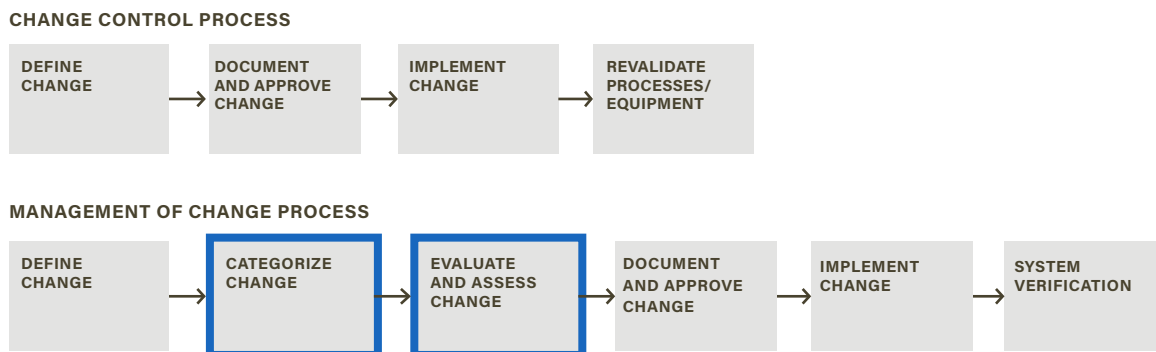
only healthcare delivery standard reviewed that has requirements for defining characteristics of processes and services, required or expected process/service output, and validation and revalidation of the ability of processes/services to achieve the planned results (European Committee for Standardization, 2017). It must be noted that DIN EN 15224 for healthcare is a European standard applicable to European healthcare organizations, and its implementation and use are not known in healthcare delivery systems otherwise. With respect to the general quality management standard (ISO 9001), no references to this standard were found in any of the healthcare-related regulations.

#### — 3.2.1.2 Change Control/Management of Change

**Management of Change (MOC)** is a best practice used to ensure that safety, health, and environmental risks are controlled when a company that is subjected to major safety hazards makes changes in their facilities, documentation, personnel, or operations. The concept of management of change is part of safety management and originates from the chemical process industry where it was determined that several catastrophic incidents were a result of mismanaged changes to processes or equipment (Chosnek, 2010; Keren, West, & Sam Mannan, 2002). Since that time, a MOC process is required by law in that sector. The purpose of the MOC process is to screen proposed changes, evaluate their potential impact on the safety of operations, and mitigate identified safety risks prior to implementation of the change (Kelly, 2013).

Change control is defined as a structured documented method of revising a policy, process, or procedure and its associated systems (Canadian Standards Association, 2016). The change control process and the MOC process include the following steps (Kelly, 2013):

**Figure 4 - Change Control Vs. Management of Change Process in Safety-Critical Industries**



The **management of change** is a component of **safety assurance** in aviation. As part of the SMS requirement, changes that could have an impact on the safety of an aviation product or service are identified, assessed, and controlled (International Civil Aviation Organisation, 2013).

Similar to aviation, a nuclear energy safety management system requires changes to be identified, justified, reviewed by relevant stakeholders and individuals knowledgeable in the field, approved, implemented, and monitored for effectiveness (Canadian Standards Association, 2012a). Nuclear energy refers to this process as “change control”.

In the blood and blood components regulations, standards, and guidelines, there are requirements for implementation of a change control program as part of the QMS and the need to revalidate processes and procedures after a change (Government of Canada, 2015b; Health Canada, 2014; Standards Council of Canada & Canadian Standards Association, 2016; WHO Expert Committee on Biological Standardization, 2017).

The CSA Z7000-18 standard for quality management and safety in perioperative settings requires healthcare organizations to establish standard operating procedures and describe the steps for identification, documentation, review, and approval of all changes to established

processes (Canadian Standards Association, 2018). Similarly, the European standard for healthcare clinical processes requires organizations to plan for changes in a controlled manner, consider the consequences of unintended changes, and mitigate adverse effects (European Committee for Standardization, 2017).

There are change control requirements in healthcare support services and healthcare delivery standards. However, these lack requirements for **proactive evaluation** and assessment of safety risks associated with proposed changes. As well, they lack the management of change process required in other safety-critical industries and safety management system standards.

### 3.2.2 In Practice

Through SME interviews, it was established that aviation and nuclear energy have management of change and process control processes in place to ensure safe and standardized practices, as described above.

In both industries, **process controls** may include having standard operating procedures, operating and maintenance manuals, and general management system manuals in place, and verification of emergency responses. Nuclear industry controls also include design control, testing, and validation.



*“...an effective change control process requires committees to include individuals who are familiar with the scope of the design and operations and who are experts in the field.”*

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Aviation **management of change** process is called Hazard Identification and Risk Assessment (HIRA), and involves having committees in place to validate changes and verify that they meet safety requirements.

Nuclear energy refers to their change control process as an **engineering change control**. Here, changes must be approved by authorized personnel including engineering, operations, and maintenance to ensure that design and safety requirements are met.

Stakeholders from both industries stated that an effective change control process requires committees to include individuals who are familiar with the scope of the design and operations and who are experts in the field.

Through our consultations with SMEs, such standards on process and change control were not found to exist in healthcare delivery. Radiation medicine within certain hospitals have implemented process and change control when introducing new technologies and processes with changes reviewed by a designated committee. However, this practice is an exception and is not generally used in healthcare delivery otherwise.

### 3.3 Risk Management

*Theme: Lack of proactive risk management and mitigation effectiveness verification in healthcare delivery*

#### 3.3.1 Regulations, Standards, and Guidelines

Safety risk management is a component of aviation safety management systems and includes **hazard**

**identification, safety risk assessment, and mitigation** (International Civil Aviation Organisation, 2013). Aviation organizations understand that human-operated and human-built systems can never be free of hazards and associated risks. As such, aviation organizations must continually identify hazards and mitigate safety risks (International Civil Aviation Organization, 2013).

Hazard identification is based on a combination of proactive, predictive, and reactive safety data collection that are described below (International Civil Aviation Organisation, 2013; International Civil Aviation Organization, 2013):

**Proactive:** Analyzing existing or real-time situations (the primary job of the safety assurance function with its audits, evaluations, employee reporting, and associated analysis and assessment processes) and actively seeking hazards in the existing processes (International Civil Aviation Organization, 2013).

**Predictive:** Gathering data to identify potential negative future outcomes or incidents, analyzing systems, processes, and the environment to identify possible future hazards and initiating mitigating actions (International Civil Aviation Organization, 2013).

**Reactive:** Analyzing past outcomes or events. Hazards are identified through investigation of safety incidents and accidents. They are used as clear indicators of system deficiencies, and therefore can be used to determine the hazards that contributed to the event or are latent (International Civil Aviation Organization, 2013).

Processes exist for analysis, assessment, and safety risk control of the identified hazards (International Civil Aviation Organisation, 2013). Examples of systems and processes that may be used to facilitate risk management in aviation are the incident reporting system that captures incidents and near misses, incident and accident analysis, and exchange of safety information. The FAA also requires organizations to conduct systems analysis where a system is defined, described, and analyzed in detail to identify all potential safety hazards (Office of the Federal Register, 2019).

To ensure continued safety of operations, aviation organizations are required to **establish safety performance indicators and targets to validate the effectiveness of the implemented safety risk controls by verifying the safety performance** against these established criteria (International Civil Aviation Organisation, 2013). Aircraft and aerodrome operators are required to **continually monitor the performance of the SMS** and have a formal process in place to identify causes and consequences of substandard performance of the SMS in operations, and address these issues through elimination or mitigation of the causes (International Civil Aviation Organisation, 2013; International Civil Aviation Organization, 2009).

As part of the nuclear energy management system standards, non-conformances or issues in a nuclear power plant are required to be immediately controlled, recorded, and assessed for significance and root cause (Canadian Standards Association, 2012a). In nuclear energy standards, it is specified that if corrective actions are taken to correct a reported non-conformance, they need to be reviewed for effectiveness. Nuclear organizations are also required to analyze their systems and processes in detail to identify all potential hazards and modes of failure and address these immediately to reduce the risk of safety incidents (Canadian Standards Association, 2017b; International Atomic Energy Agency, 2016b).

Healthcare support services have requirements in place for identification, investigation, and evaluation of errors, accidents, deviations from normal operating procedures, and implementation of corrective actions in response to identified non-conformances (Canadian Standards Association, 2017a; Standards Council of Canada & Canadian Standards Association, 2016).

In healthcare delivery, the CSA Z7000-18 standard which is applicable to the perioperative environment and the ISO 15189 standard for healthcare delivery include requirements for identification, investigation, documentation, evaluation, and correction of deviations from policies and procedures, which have led or could lead to adverse events (Canadian Standards Association, 2018; European Committee for Standardization, 2017). Evaluating near misses, incidents, adverse events, and clinical risks are all considered methods of evaluating the performance of the QMS (European Committee for Standardization, 2017).

As previously stated, there are no regulatory or standard requirements for safety management system implementation in healthcare support services and healthcare delivery. However, within the healthcare support services quality management system requirements, establishments are required to monitor the results of implemented quality corrective actions to verify their effectiveness in overcoming the identified problems (Canadian Standards Association, 2012b; Health Canada, 2014; Standards Council of Canada & Canadian Standards Association, 2016). The ISO standard for healthcare delivery requires evaluating the effectiveness of actions taken to address risks and opportunities (European Committee for Standardization, 2017).

Although healthcare support service and healthcare delivery standards make references to investigation and evaluation of deviations from normal operations, these are in the context of quality deviations and not safety focused. Healthcare delivery standards lack requirements for hazard identification, proactive risk assessment, and mitigation effectiveness verification.





*“... lessons learned and experiences, whether positive or negative, are not regularly shared among healthcare organizations.”*

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The Canadian Patient Safety Institute (CPSI) has published a framework for incident analysis which describes the processes involved in analysis of patient safety incidents. This framework includes processes such as monitoring and assessing the effectiveness of recommended corrective actions after implementation in response to an adverse event (Canadian Patient Safety Institute, 2012). However, this document is not a standard and is primarily focused on reactive risk management as opposed to proactive risk management.

### 3.3.2 In Practice

Processes surrounding reactive risk management — including incident and accident analysis, and recommending and implementing corrective actions — exist in all three industries. Healthcare delivery has improved in incident reporting and continues to encourage and promote more near-miss and incident reports. However, healthcare delivery can benefit from improved proactive risk management, incident and accident analysis, mitigation development, and mitigation effectiveness verification.

Aviation and nuclear energy have safety management standards and guidelines that include strong risk assessment processes, various mitigation plans, and an overall **closed risk management loop** where effectiveness of mitigations is verified. This is in contrast to healthcare practice where mitigations are commonly implemented however their effectiveness in reducing patient safety risk is left unmeasured, thus constituting an open risk management loop.

The aviation and nuclear industry’s risk assessment process and mitigation planning are driven by safety requirements and are not normally limited by challenges such as cost, lack of resources, and time. This is in contrast to healthcare where cost, ease of implementation, general resourcing, and time constraints influence outcomes of risk assessment and mitigation development.

Not all nuclear facilities and airports are designed and built the same way or use the same equipment or technologies, yet past experiences and lessons learned are shared among nuclear power plants and among airlines and airports. In contrast, lessons learned and experiences, whether positive or negative, are not regularly shared among healthcare organizations.

Risk management in aviation and the nuclear industry consists of the following steps:

#### **Hazard Identification**

Methods of hazard identification in aviation vary and range from **proactive hazard identification** to **lessons learned from adverse events**, and **continuous review of regulations and standards** to identify changes and anticipate new hazards.

The nuclear industry also has several hazard identification methods, examples of which are **job hazard assessment** or **job safety assessment**, **observations in the field**, and the **philosophy of SAFER dialogue**.



SAFER stands for:

- **Summarize** the scope/critical steps
- **Anticipate** errors for each critical step by identifying the error precursors and conditions or human factors around a task that can influence someone's ability to be able to successfully carry out that task
- **Foresee** worst-case consequences for each of the critical steps by thinking about the actions that need to be taken should an event occur
- **Evaluate** your risk controls in their ability to prevent, catch and recover, or mitigate consequences
- **Review** previous lessons learned and experiences for the tasks and the critical steps to verify all hazards have been identified and mitigated

In both aviation and nuclear energy, the hazard identification process is integrated with the management of change process, as changes have the potential to introduce new hazards to the system.

Similar to the **management of change**, which requires involvement of the right people, hazard identification is also far more effective if stakeholders are correctly identified and involved in the process of identifying new hazards.

Proactive hazard identification is not widely practised in healthcare. The only known hazard identification technique that was raised by the stakeholders interviewed was near-miss reporting.

### ***Risk Assessment and Mitigation***

Stakeholders from both the aviation and nuclear energy industries explained that risks are evaluated and ranked based on their severity and probability of occurrence. Aviation also has a hazard registry which is used to inventory new and previously identified hazards. These hazards are regularly reviewed for trends and changes in risk ranking to ensure risks are maintained to *As Low As Reasonably Practicable* (ALARP). Proper assessment of an identified hazard or event is important

for implementing effective and strong mitigations. In response to the outcomes of the risk assessment, both industries implement mitigations that vary in effectiveness and strength.

In response to identified hazards or an accident, aviation implements two types of mitigating solutions: **short-term solutions** and **long-term solutions**. Short-term solutions include administrative controls and long-term solutions consist of equipment/process redesign or implementation of a new safety system that would effectively reduce or eliminate safety hazards. Short-term solutions allow aviation organizations to temporarily mitigate the hazards while they work towards developing and implementing stronger and more robust risk control strategies.

Our nuclear stakeholders explained that, "the nuclear industry implements various mitigations that may include a combination of administrative controls, engineering controls, substitution, elimination, and physical barriers."

Aviation and nuclear energy organizations invest time and resources in managing changes and risks that are of greater consequence. For example, nuclear energy mitigates hazards that are of higher risk to safety and places hazards that are of lower consequence and risk into trending and monitoring. Unlike aviation and nuclear energy, adverse events and near misses in healthcare are not investigated or resolved properly. Efforts are made in resolving most events by severity, regardless of whether they are of high risk or low risk, indicating a lack of proper risk assessment. Stakeholders have identified that a majority of the implemented mitigations in healthcare delivery are administrative controls such as updating policies and retraining staff.

### ***Effectiveness verification***

In a closed-loop risk management system, the aviation and nuclear energy industries designate committees to review trends and data from the implemented mitigation and evaluate its effectiveness in eliminating or reducing the safety hazard. If the mitigation in question is not

effective in reducing or eliminating the hazard and the hazard still exists, then new mitigations are required to be implemented. This process continues until the safety hazard is eliminated or mitigated to an acceptable level.

Unlike aviation and nuclear energy, the risk management loop in healthcare delivery is often open as a result of the lack of follow-up on implemented mitigations to ensure that they are successful in reducing patient safety hazards. In healthcare delivery, such outcome data are not routinely collected or analyzed, which may result in adverse events recurring.

### 3.4 Fatigue Management

*Theme: Lack of fatigue management practices in healthcare delivery*

#### 3.4.1 Regulations, Standards, and Guidelines

Worker fatigue is considered a safety hazard in safety-critical industries that operate on a 24-hour basis. It is also acknowledged in safety-critical industries that fatigue is inevitable, cannot be eliminated, and must be managed using a fatigue risk management system (FRMS) (International Air Transport Association, International Civil Aviation Organization, International Federation of Airline Pilots' Association, 2015).

Fatigue is defined as "a physiological state of reduced mental or physical performance capability resulting from sleep loss, extended wakefulness, circadian phase, and/or workload (mental and/or physical activity) that can impair a person's alertness and ability to perform safety-related operational duties" (International Civil Aviation Organization, 2010a).

##### — 3.4.1.1 Fatigue Management in Aviation

In aviation, a fatigue risk management system (FRMS) is defined as "a data-driven means of continuously monitoring and managing fatigue-related safety risks, based upon scientific principles and knowledge as well as operational experience that aims to ensure relevant personnel are performing at adequate levels of alertness" (International Civil Aviation Organization, 2010a).

Negative impacts of fatigue on an aviation flight crew's performance are well-studied. Fatigue is the primary

reason why the aviation industry enforces limitations on flight time, flight duty period, duty period, and rest period (International Civil Aviation Organization, 2010a). There are standards, guidelines, and fatigue risk management toolkits that are in place to enable aviation organizations to effectively manage fatigue (International Air Transport Association, International Civil Aviation Organization, International Federation of Airline Pilots' Association, 2015; International Civil Aviation Organization, 2010a, 2016; Transport Canada, 2007a, 2007b, 2007c, 2007d). As an example, Transport Canada, which regulates Canadian aviation organizations, has a fatigue risk management system toolbox (Transport Canada, 2007a) that includes guidelines intended for employers and employees to enhance their knowledge of fatigue and identify fatigue symptoms and the actions that can be taken to self-regulate fatigue (Transport Canada, 2007b, 2007d).

The International Air Transport Association (IATA) in collaboration with the International Federation of Airline Pilots' Association (IFALPA) and ICAO have published guidance (International Air Transport Association, International Civil Aviation Organization, International Federation of Airline Pilots' Association, 2015) for fatigue management of airline operators based on the ICAO's Annex 6 (International Civil Aviation Organization, 2008, 2010a, 2016). This guideline details the basic science behind sleep, factors affecting sleep quality, the impact of reduced or low-quality sleep, operational and organization components of an FRMS, examples of fatigue hazards, and a detailed description of fatigue risk management processes, including hazard identification, risk assessment, and mitigations (International Air Transport Association, International Civil Aviation Organization, International Federation of Airline Pilots' Association, 2015).

In line with the Transport Canada guidelines, the ICAO standard (Annex 6 to the Convention on International Civil Aviation: Operation of Aircraft — Part 1) (International Civil Aviation Organization, 2010a) requires aviation organizations to routinely assess adequacy of established maximum work hours and minimum rest periods and establish new maximum



*"... in nuclear energy ... any shift changes must go through a change control process and be assessed for impact on worker fatigue and safety."*

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and minimum limitations to increase safety. The FRMS is subject to the safety assurance processes described in the Safety Management System section, and as such when changes are proposed to be made to these limitations, risks associated with these changes have to be assessed for impact on safety (International Civil Aviation Organization, 2010a).

#### — 3.4.1.2 Fatigue Management in Nuclear Energy

Fatigue management in the nuclear energy industry in Canada is regulated by the CNSC. CNSC has published a regulatory document titled REGDOC-2.4.4, Fitness for Duty: Managing Worker Fatigue (Canadian Nuclear Safety Commission, 2017), which states that fatigue-associated risks must be managed through a system that utilizes similar principles as other nuclear energy management systems, and establishes and justifies limitations on hours of work and rest periods based on knowledge and scientific principles. It is understood that there are factors outside of work in someone's personal life that may affect fatigue and therefore management and workers share the responsibility of reporting and managing fatigue. One recommendation for managing worker fatigue is to schedule safety-critical tasks outside of fatigue peak hours (primarily between 2 am and 6 am).

As with the aviation industry, the nuclear energy regulatory document requires that any shift changes go through a change control process and be assessed

for impact on worker fatigue and safety. **In the case of a serious safety event where worker fatigue could have played a factor, the involved worker's schedule and rest periods must be obtained, assessed, and included in the incident report.** Finally, periodic assessment of the fatigue management system must be completed to ensure that the shift hours and rest periods are sufficient and that there are appropriate levels of resources available to perform the tasks (Canadian Nuclear Safety Commission, 2017).

Similar to Canada, the United States also has regulations (U.S. Nuclear Regulatory Commission, n.d.) on fatigue management in the nuclear industry. Per these regulations and relevant guidance documents, work hours are controlled and limited with a specified minimum rest period required after each work period. The regulations and guidance document also state that work schedules should be designed in a way that prevents worker fatigue. Fatigue assessments are required to be completed in four circumstances (U.S. Nuclear Regulatory Commission, n.d.):

1. There is cause to believe that a worker is fatigued
2. The worker has self-declared their fatigue
3. An accident has occurred as a result of worker fatigue
4. Follow-up to (1) where there was cause to believe that a worker was fatigued

Additionally, International Atomic Energy Agency (IAEA) references worker fatigue in its standard on conduct of operations at nuclear power plants (International Atomic Energy Agency, 2008) stating that managers should pay particular attention to signs of fatigue and should minimize fatigue by limiting work hours (International Atomic Energy Agency, 2008).

#### — 3.4.1.3 Fatigue Management in Healthcare

Research on the effects of fatigue on a healthcare provider's performance suggests that longer work hours are associated with declining performance, increased likelihood of mistakes, and the occurrence of near misses (Dorrian et al., 2006; Gander, Millar, Webster, & Merry, 2008; Geiger-Brown et al., 2012; Montgomery, 2007). A pilot study on the relationship between work and sleep on Australian nurses showed that nurses slept fewer hours on workdays compared to non-workdays. This decrease in sleep hours negatively affected nurses' performance at work and was associated with an increase in errors and near-miss events in care delivery (Dorrian et al., 2006). Increased shift length and an increased number of days where healthcare providers work successive 12-hour shifts leads to reduced sleep hours and less chance of physical and cognitive recovery (Geiger-Brown et al., 2012).

Increased fatigue levels can also negatively impact tasks that are longer in duration and need attention to detail such as patient monitoring, documentation, and medication administration (Barker & Nussbaum, 2011). Similar results have been observed with residents and specialists where sleep loss was associated with increased rates of surgical complications and errors and increased duration of surgical procedures (Montgomery, 2007). Fatigue also results in reduced motivation, confusion, lapses in memory, ineffective communication, slow processing and decision making, reduced personal well-being and health, and feeling indifferent with a lack of empathy (Dubeck, 2014; Resident Doctors of Canada, 2012; The Joint Commission, 2011).

Healthcare workers' fatigue is linked with increased risk of adverse events and compromised patient safety (Dubeck, 2014; The Joint Commission, 2011). Given the research that has been done to date on fatigue and healthcare workers' performance, in 2003, the Accreditation Council for Graduate Medical Education (ACGME) published a standard for physicians in training (Dubeck, 2014; The Joint Commission, 2011). This standard has established requirements regarding the maximum number of hours a physician in training can work (80 hours/week) and the use of fatigue

**Table 2 - Fatigue Risk Levels: 7 Day Period From Resident Doctors of Canada: Fatigue Risk Management Toolkit (Resident Doctors of Canada, 2018)**

LOWER RISK	SIGNIFICANT RISK	HIGHER RISK
Less than 50 hours worked	50-70 hours worked	More than 70 hours worked
No more than 10 consecutive hours in any one period	Up to 14 consecutive hours in any one period	14 or more consecutive hours worked at least twice
Three or more short breaks taken during daily working hours	One or two short breaks during daily working hours	No short breaks during daily working hours
Little or no unscheduled extra work	More than 10 hours extra unscheduled work	More than 20 hours unscheduled extra work
Scheduled on call for less than 3 days in seven days	Scheduled on call for 3 days or more in a 7 day period	Scheduled on call continuously for more than 7 day period
No night work	At least 2 nights of work or extended hours into the night	At least 3 nights of work or extended hours into the night
Minimum 10 hour breaks between work periods and 2 days free of work	Minimum 10 hour breaks between work periods and one day free of work	Less than minimum 10 hour break on at least two work periods and no full day free of work



management strategies (Accreditation Council for Graduate Medical Education, 2011; Dubeck, 2014; The Joint Commission, 2011).

The European Working Time Directive (WTD) is a legal document under European Union (EU) and domestic UK legislation that is applicable to consultants, doctors outside training, doctors in training, and other National Health Service (NHS) staff (Canadian Medical Association, 2014; European Union, 2003). Under this directive, the maximum working hours are set at 48 hours per week with a maximum of 13 continuous duty hours. Australia and New Zealand have adopted very similar work-hour limits for their resident physicians (Resident Doctors of Canada, 2012). Canada has also set work-hour limits for residents; however, the limit on resident work hours is not consistent across Canada. As an example, there is a guidance document stating that resident work hours in Manitoba are limited to 89 hours per week, whereas Maritime provinces have a limit of 90 hours per week, and Quebec has a limit of 72 hours per week averaged over 28 days (Resident Doctors of Canada, 2012).

The Resident Doctors of Canada have published a fatigue risk management toolkit to be used as a resource by Canadian medical education institutions to develop fatigue risk management policies and mitigation strategies (Resident Doctors of Canada, 2018). A "fatigue risk checklist" is an example of a tool provided where fatigue risk can be ranked as "low", "significant", or "high" based on the number of hours worked in a week, the number of days off, and the breaks in between shifts (Figure 2). If the countries mentioned above were to be evaluated using these criteria, Canada and the United States would rank as having a higher fatigue risk while the European Union and Australia would rank as having a lower fatigue risk.

Queensland Health in Australia has a policy to manage worker fatigue and its related risks to employees and patients through the application of a risk management framework (Queensland Health, 2014). Related to this policy, and also published by Queensland Health, is a FRMS resource pack which defines fatigue and provides an overview of the FRMS development

and implementation process and a comprehensive definition, explanation, and examples of a 5-level controls framework, similar to what is observed in the aviation FRMS implementation guide (Dubeck, 2014; Queensland Government & Queensland Health, 2009). Implementation status and effectiveness assessment of this FRMS resource pack are not known.

### 3.4.2 In Practice

Fatigue management is regulated in aviation, and there are standards and requirements on the maximum number of work hours and the minimum rest period that need to be satisfied by aviation organizations. Fatigue is considered a safety risk in aviation and is taken into account during risk assessment.

Similarly, in nuclear energy, work cycles are regulated to control worker fatigue. Controls are in place to ensure that employees cannot exceed the maximum number of work hours by timing them out and preventing them from being able to enter the facility.

Worker fatigue is an area of concern in healthcare delivery, specifically in trainees. Rules have been created around the number of hours that trainees can work; however, these rules serve only as guidelines. A number of physicians were interviewed, and they were unclear about the specifics of the guidance for staff. **The pervasive practice in healthcare delivery is that providers need to learn to function under fatigued conditions.** Worker fatigue is often not identified as a hazard or a risk factor during investigations due to professional culture issues and the understaffing that restricting hours would cause in the delivery of care.

## 3.5 Reliability of Safety-Critical Tasks

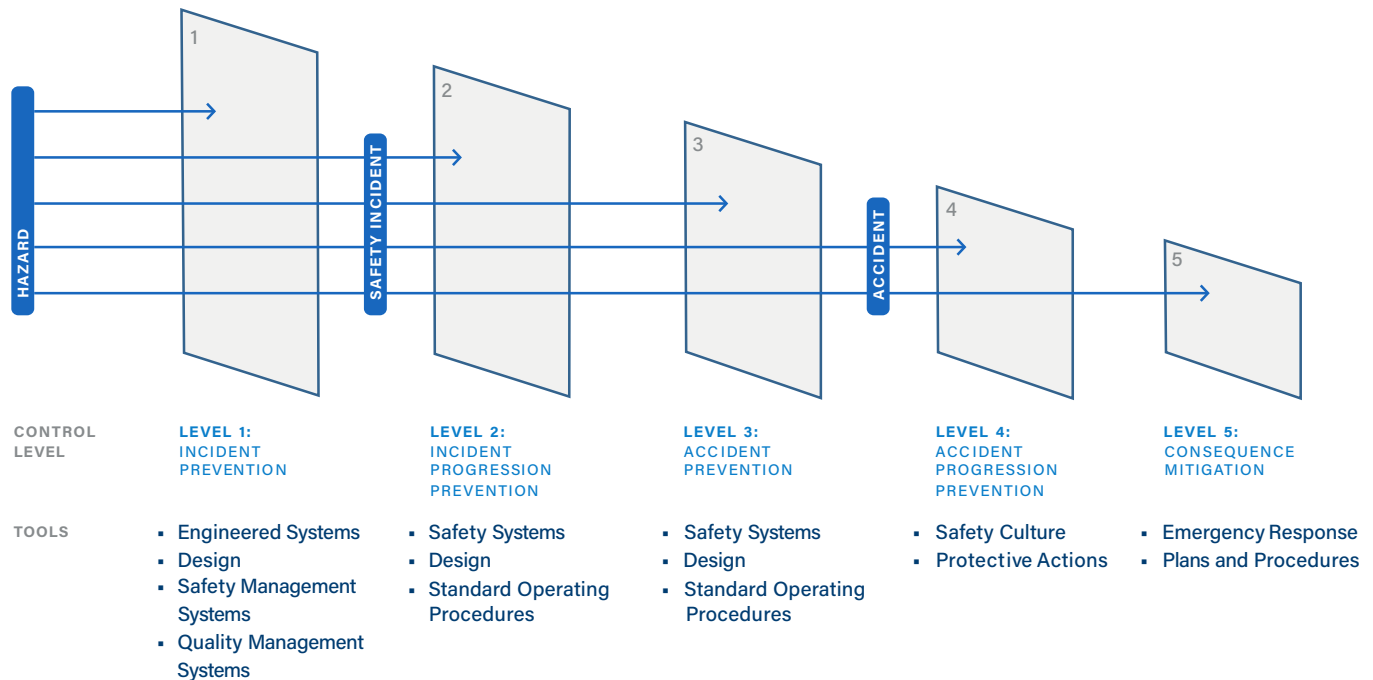
*Theme: Lack of reliability of safety-critical tasks in healthcare delivery*

### 3.5.1 Regulations, Standards, and Guidelines

Nuclear energy standards state that reliability in nuclear power plants can be achieved through concepts of redundancy, physical separation, and functional independence (Canadian Standards Association, 2017b; International Atomic Energy Agency, 2016b).



**Figure 5** - “Defense in Depth” as Found in Nuclear Energy Safety (International Atomic Energy Agency, 2016)



Redundancy in nuclear power plant design can be achieved through the installation of redundant systems or safety components. Having redundant components can provide assurance that in the event of a safety system malfunction, the redundant (back-up) safety system can be relied upon (Canadian Standards Association, 2017b; International Atomic Energy Agency, 2016b).

In the context of nuclear plant design and operation, nuclear safety systems, safety systems and process systems, and redundant components of safety systems need to be **separated and independent** of one another (Canadian Standards Association, 2017b; International Atomic Energy Agency, 2016b). Separation and independence can provide assurance that a failure in a process system will not result in failure of a safety system since these systems are functioning independently of each other (Canadian Standards Association, 2017b; International Atomic Energy Agency, 2016b).

Similarly, independence of engines from other engines, from the main electrical supply, and from associated systems are specified in the aviation standard (International Civil Aviation Organisation, 2005). In the event that an engine fails, it will not compromise the safety of the aircraft because the systems have been separated (International Civil Aviation Organisation, 2005).

Redundancy, separation, and independence form the basis of the concept of **defence in depth** (Figure 5). Defence in depth can be applied to all safety-related activities, and ensures that behavioural, organizational, and technological (design-related) activities are subject to levels or layers of protection (redundancy) that are independent of each other (i.e. independence and separation) (International Atomic Energy Agency, 2006, 2016b). The idea behind having independent levels of protection in a process is that if one level fails, the error can be captured, corrected, or contained before it can progress further in the system and cause adverse events that cannot be reversed (International Atomic Energy Agency, 2006, 2016b).

Defence in depth is a combination of the following (International Atomic Energy Agency, 2006):

- An effective management system and commitment to safety
- Good design, engineered features, and control processes
- Reliable systems, processes, and materials
- Comprehensive operational and accident management procedures
- A strong safety culture

Nuclear energy also defines several symptoms indicative of a declining safety culture and reduced reliability. Some notable ones are listed below (International Atomic Energy Agency, 2009):

- Lack of a systematic approach to safety — unclear accountabilities, poor risk assessment processes, lack of a management of change process
- Procedures are not regularly reviewed and updated
- Incidents are not analyzed in depth and lessons are not learned — problems recur, indicating that the fundamental cause (or causes) has (have) not been properly identified
- No actions are taken or implemented in order to eliminate root causes
- Excessive overtime, lack of qualified and experienced personnel, increased use of contractors to perform key organizational activities for long periods of time
- Increasing numbers of conscious deviations from rules, e.g. shortcuts
- An increasing backlog of corrective actions — corrective actions exceeding their target date for implementation
- Lack of recognition that everyone shares a responsibility for safety; lack of safety ownership
- Isolationism — safety practices and standards become unrelated to best practices and standards in the industry whereby the organization begins to operate in a self-referencing mode

### 3.5.2 In Practice

Aviation and nuclear energy ensure the reliability of their processes and technologies. Nuclear energy has comprehensive and detailed reliability standards and requirements whereas reliability assessment is uncommon in healthcare delivery.

Aviation must ensure the reliability of its processes as part of its regulatory requirements. There had been several incidents due to lack of redundancy, which has prompted aviation organizations to increase redundancy and therefore the reliability of their processes. Some examples are aerodrome infrastructure redundancy requirements for air navigation aids, airfield lighting, airfield surfaces, power sources, and communication equipment.

Nuclear energy is obligated to ensure reliable operations as their standards speak to having **redundancy**, **separation**, and **independence of systems**. There are two types of reliability in nuclear industry: **equipment reliability** and **human reliability**. Both equipment reliability and human reliability can be achieved by applying the concept of **defense in depth** (as described above). Defence in depth is also supported by understanding oversight and cultural controls, which encourage and reinforce human behaviour and reduce the likelihood of an error progressing to an event.

## 4 Results of Member-Checking Process

A member-checking exercise was conducted in the form of a focus group involving healthcare stakeholders from various disciplines and functions from Ontario-based organizations including the University Health Network (UHN), St. Michael's Hospital, CSA Group, Sinai Health System, The Hospital for Sick Children, and UHN Healthcare Human Factors. A total of 15 stakeholders from disciplines such as standards research, patient safety, human factors, nursing, professional practice, policy development, emergency medicine, internal medicine, and cardiology attended the focus group.



*“... there is a high level of individual and organizational autonomy in healthcare compared to aviation and nuclear energy, lack of incentivized training, and lack of reliability, resilience, and systems thinking.”*

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The purpose of the member-checking focus group was to present the findings of the research, review the identified themes (described in detail above) with the stakeholders, identify the themes that resonated with the stakeholders, and determine if the direction taken with this research is appropriate.

Overall, participants agreed that the presented themes resonated with them with respect to their experience in a healthcare setting. They agreed that there is a high level of individual and organizational autonomy in healthcare compared to aviation and nuclear energy, lack of incentivized training, and lack of reliability, resilience, and systems thinking.

One issue that participants stated as a challenge in healthcare is constant interruptions while tasks are being performed. These interruptions include pagers going off, phone calls, and colleagues requesting help with a task.

Additional comments on each theme are summarized below:

#### ***Safety Management in Healthcare Delivery***

Participants stated that lack of a safety management system in healthcare delivery resonated with them. Concerns around lack of well-defined roles, responsibilities, accountabilities, and authorities were discussed. Another issue raised was the lack of communication about who the decision makers are and what the decision-making process is in healthcare organizations.

There were discussions on the lack of safety communication within all areas of an organization. Although forms of best-practice communications exist, such as safety huddles, they often do not take place across the organization.

Another major roadblock to safety management was identified as a lack of sharing safety and incident learnings in a healthcare organization or between healthcare organizations, possibly due to high levels of organizational autonomy.

Additionally, healthcare workers are not incentivized to keep their training current, which leads to a lack of recurrent training within a job role.

#### ***Lack of control processes to ensure uniform, consistent practice in healthcare delivery***

Participants agreed that there is a lack of process control in healthcare delivery. Although there are “best practices” in healthcare, there are many different ways of performing a delivery process/procedure, and healthcare workers choose to perform processes their way rather than follow established procedures. Even within blood processing laboratories, for which standards do exist, there are certain laboratories that follow independent procedures. Pharmacy (fulfillment) was identified as the most regulated and standardized department given that they do conduct internal and external audits and have built in cross-checks and other control processes as well as documentation.

It was mentioned that there is a lack of investment in time and resources in implementing control processes in healthcare delivery due to the volume of work. Rapid and uncontrolled changes prevent proper implementation of control processes and may fatigue the organization.

Handovers between shifts was mentioned by participants as one of the processes for which standardization could benefit healthcare organizations and patients. Handovers are thought of as structured and controlled in aviation and nuclear energy, whereas in healthcare there is no standardized or defined process to complete handovers.

The issue of variability in healthcare delivery processes was raised often. Variation may be viewed as either unnecessary variation of care practice that may occur, or the variation in the patient population that requires the delivery of care. Unnecessary variation can exist where evidence for standardization is well established. This type of variation is considered unjustifiable and may be eliminated using quality improvement methodology and processes. Another type of variation in practice may be a result of variation in the patient population. Many scenarios in healthcare do not have a “right” answer or a standard way of approaching them because the evidence base is largely poor and applies to only a small fraction of patients. Some patients in healthcare would be considered “off-label” with no standard treatment.

Variation in patient population and lack of an evidence base for many of the patients were mentioned as reasons why controlling and standardizing processes in healthcare delivery is challenging. However, participants agreed that process control may be applied to **high-risk** processes.

#### ***Lack of proactive risk assessment and mitigation effectiveness verification in healthcare delivery***

Participants identified that many of the aviation and nuclear energy proactive hazard identification techniques do exist with respect to healthcare **worker safety**, but not necessarily for patient safety. Lessons learned from previous adverse events are identified, but they are not shared within the organization. **Lack**

#### **of safety accountability in healthcare delivery was raised again.**

Root-cause identification and analysis in healthcare delivery relies on too many meetings and may take weeks or months to complete. Another challenge mentioned by participants with respect to risk management was that risk and risk aversion/tolerance is not very well defined and risk itself is not quantified in healthcare delivery.

Lack of mechanisms or processes to conduct just-in-time risk assessments was identified as yet another safety assurance challenge in healthcare delivery.

#### ***Lack of fatigue management practices in healthcare delivery***

Participants agreed that healthcare worker fatigue is not tracked, reported, or identified as a hazard or risk factor due to professional culture issues and the resulting understaffing. Stakeholders identified that the workload as well as a lack of flexibility and back-up in the healthcare system results in downstream implications of staff getting called in to work.

The culture that medicine has created results in unrealistic expectations among nurse practitioners, in which they are expected to also work longer hours.

Healthcare’s approach to fatigue management is one that interprets fatigue as a character flaw rather than a system issue. The onus is placed on residents/staff and they are advised to become more resilient. Essentially the responsibility of fatigue falls on the residents and staff, who are expected to learn coping mechanisms to deal with fatigue.

#### ***Lack of reliability of safety-critical tasks in healthcare delivery***

Participants mentioned that the capacity to separate safety systems and process systems does not currently exist in healthcare delivery. Possible lack of reliability may be attributed to creating processes and systems that place staff in moral distress due to the expectations to continue with a specific task.

## 5 Example Solution(s)

### ***Safety Management in Healthcare Delivery***

Implementation of a safety management system is challenging and will take time. However, certain components of the safety management system, such as the ones described below, can be implemented separately leading to implementation of the complete safety management system in the future.

#### ***Lack of control processes to ensure uniform, consistent practice in healthcare delivery***

The potential solutions listed below can address this gap in healthcare delivery:

1. Implementation of a management of change process in high-risk areas within healthcare delivery (an example of a high-risk process is handovers).
2. For this to be effective, high-risk processes in high-risk areas need to be defined.
3. The management of change process can be applied to modifications of existing high-risk processes, introduction of new processes and technologies, and modifications to existing technologies.

#### ***Lack of proactive risk management and mitigation effectiveness verification in healthcare delivery***

The following are potential solutions to improve risk assessment and mitigation effectiveness verification in healthcare delivery:

1. Reviewing the existing incident reporting database to identify recurring incidents and their respective areas/units.
2. Mapping the identified processes and identifying potential hazards.
3. Performing proactive risk assessments on the identified hazards and categorizing risks based on a risk assessment matrix (adopt from Aviation, Nuclear Energy, or Medical Device Design).
4. Mitigating risks using a combination of administrative and engineering controls.

5. Monitoring performance of the controls and recurring incidents (if any) to adjust the risk control strategy until risks are eliminated or mitigated to a non-recurring level.

#### ***Lack of fatigue management practices in healthcare delivery***

This gap may be the most challenging to eliminate, but potential solutions include:

1. Initiating fatigue management by designing work schedules for those directly responsible for patient care. Work schedules should be designed based on already existing guidelines (nurses/residents).
2. Increase education on fatigue and its impact on worker performance and health, and mandating, through a self-reporting policy, to have workers report when they are fatigued and not fit for duty.
3. Mandating, through a fatigue risk management system policy, to have fatigue management as a required practice.

#### ***Lack of reliability of safety-critical tasks in healthcare delivery***

This gap may be eliminated by:

1. Increased education in reliability and the defence-in-depth model as applicable to equipment and human performance.
2. Applying the defence-in-depth concept to incidents that are being investigated to identify areas where reliability of tasks can be increased by adding additional, separate safety systems.

## 6 Conclusions and Recommendations

The learnings from the safety-critical industries of aviation and nuclear energy with respect to certain safety management system elements, such as change and process control, are not practiced in healthcare delivery.

Quality management systems defined and used for healthcare settings do not actively identify, assess, and mitigate safety risks. It was evident from the literature that there is a lack of requirements for implementation



of a safety management system both within standards, regulations, and guidelines and in practice in healthcare delivery.

To validate literature review findings, stakeholders in aviation, nuclear energy, and healthcare delivery were identified and interviewed. Stakeholders in healthcare delivery confirmed that there are no controls of processes across healthcare settings. Healthcare service delivery systems are largely under-designed in an ad hoc manner. Healthcare organizations and practitioners have a high degree of autonomy in how they deliver care, which is in stark contrast to aviation and nuclear energy, where there is the regulated practice of engineered systems that assume controls, measures, and verification of designed outcomes. Some forms of care delivery such as radiation medicine have process control and change control measures implemented, but these are exceptions and there is no mandate for this practice.

Resources and time are spent on risks that would rank lower on a risk matrix as opposed to addressing hazards that are of greater consequence. Weak, easy to implement, and less resource-intensive mitigations are

relied upon and evaluation of the effectiveness of these mitigations is rarely completed in healthcare delivery organizations. Worker fatigue is often not identified as a hazard or a risk factor during investigations due to professional culture issues and the understaffing that restricting hours would cause in the delivery of care.

Given the safety-critical nature of healthcare delivery and the lack of implemented safety management systems, it is recommended that a standard be developed to address the noted safety deficiencies in healthcare organizations and the regulation of their practitioners. A safety management system standard for healthcare delivery would address the gaps in rigour that are currently present in practice at the individual and organizational level.

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## CSA Group Research

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In order to encourage the use of consensus-based standards solutions to promote safety and encourage innovation, CSA Group supports and conducts research in areas that address new or emerging industries, as well as topics and issues that impact a broad base of current and potential stakeholders. The output of our research programs will support the development of future standards solutions, provide interim guidance to industries on the development and adoption of new technologies, and help to demonstrate our on-going commitment to building a better, safer, more sustainable world.