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

by

Andia Toomari

A thesis submitted in conformity with the requirements for the degree of Master of Health Science, Clinical Engineering
Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Master of Health Science, Clinical Engineering
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University of Toronto
2019

Abstract

Healthcare, as a safety-critical industry, has often been contrasted with aviation and nuclear energy. Though safety tactics learned from aviation and nuclear energy have proven effective, healthcare continues to have higher number of preventable serious adverse events in comparison to aviation and nuclear energy.

A mixed-method study was conducted and revealed that aviation and nuclear energy have international organizations which develop standards to harmonize operations globally. According to these standards, there are explicit regulatory requirements within aviation and nuclear energy, to implement safety management systems at the organizational level. Application of safety management systems to the extent implemented in aviation and nuclear energy has not been fully investigated or applied in healthcare practice.

Recommendations include but are not limited to the development and implementation of a safety management system standard which includes process control, management of change, proactive hazard identification and risk management, fatigue management, and reliability analysis of safety-critical tasks.
Acknowledgments

I would like to thank my thesis supervisor Dr. Joseph Cafazzo, for trusting me with this research and for his support and guidance for the past two years. I would also like to thank my thesis committee members, Dr. David Jaffrey, Dr. Stephen Breen, Dr. Amanda Mayo, and Dr. Patricia Trbovich for their time and expertise throughout this research.

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At Healthcare Human Factors, I would like to thank Anna Yuan for all her hard work and effort in coordinating all meetings and presentations related to this research. I would also like to thank Kelsey Hannon for all her help and her wonderful design of some of the figures and tables in this thesis. Many thanks to other members of the human factors team for attending my presentations, providing constructive feedback, asking questions, and expressing interest in my work.

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Two years ago, I decided to quit my full-time job and return to school to pursue a graduate degree in a field I knew very little about, Clinical Engineering. This would not have been possible without the help and support of my managers Gerry Marasigan and Dilpreet Puar and all my wonderful SNC-Lavalin colleagues and friends who encouraged and celebrated the idea. Thank you to Mani for planting the idea in my head in the first place!

Finally, I would like to express my gratitude and many thanks to my biggest supporters, my wonderful parents and my partner in all adventures, Nawid. Thanks for always cheering me on and giving me encouragement when I need it most! Thank you for always proof-reading my reports and listening to my presentations even if you had no idea what I was going on about!
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<td>CAR</td>
<td>Canadian Aviation Regulation</td>
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<tr>
<td>CNSC</td>
<td>Canadian Nuclear Safety Commission</td>
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<tr>
<td>CPOE</td>
<td>Computerized Physician Order Entry</td>
</tr>
<tr>
<td>CPSI</td>
<td>Canadian Patient Safety Institute</td>
</tr>
<tr>
<td>CSA</td>
<td>Canadian Standards Association</td>
</tr>
<tr>
<td>DOE</td>
<td>Department of Energy</td>
</tr>
<tr>
<td>EASA</td>
<td>European Aviation Safety Agency</td>
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<tr>
<td>FAA</td>
<td>Federal Aviation Administration</td>
</tr>
<tr>
<td>FAR</td>
<td>Federal Aviation Regulation</td>
</tr>
<tr>
<td>FRMS</td>
<td>Fatigue Risk Management System</td>
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<tr>
<td>HC</td>
<td>Health Canada</td>
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<tr>
<td>HQO</td>
<td>Health Quality Ontario</td>
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<tr>
<td>IAEA</td>
<td>International Atomic Energy Agency</td>
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<tr>
<td>IATA</td>
<td>International Air Transportation Association</td>
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<tr>
<td>ICAO</td>
<td>International Civil Aviation Organization</td>
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<tr>
<td>MOC</td>
<td>Management of Change</td>
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<tr>
<td>NRC</td>
<td>Nuclear Regulatory Commission</td>
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<tr>
<td>NSCA</td>
<td>Nuclear Safety and Control Act</td>
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<tr>
<td>NTSB</td>
<td>National Transportation Safety Board</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>OPIS</td>
<td>Oncology Patient Information System</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
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<tr>
<td>SARP</td>
<td>Safety and Recommended Practices</td>
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<tr>
<td>SME</td>
<td>Subject Matter Expert</td>
</tr>
<tr>
<td>SMS</td>
<td>Safety Management System</td>
</tr>
<tr>
<td>SSP</td>
<td>State Safety Programme</td>
</tr>
<tr>
<td>TCCA</td>
<td>Transport Canada Civil Aviation</td>
</tr>
<tr>
<td>TSB</td>
<td>Transportation Safety Board</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>WHO</td>
<td>The World Health Organization</td>
</tr>
</tbody>
</table>
1 Introduction

1.1 Background and Rationale

The high incidence of morbidity and mortality due to preventable adverse events continues to stymie safety experts [1], [2]. Although there is an ongoing debate as 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 [1], [3]–[5].

After 20 years of effort since the landmark Institute of Medicine study on patient safety [6], 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” [7], [8].

Aviation is a safety-critical industry with a notable record. In 2015, the total number of passengers carried on scheduled service flights was 3.5 billion with 92 accidents and 474 fatalities [9]. Contrast this with healthcare, where 421 million people are hospitalized in the world annually with approximately 42.7 million adverse events during these hospitalizations [10]. In Canada alone, more than 138,000 acute care hospitalizations in 2014–2015 involved occurrences of harm [11].

There have been a number of learnings from aviation and nuclear energy safety practices that have been applied to healthcare. These include the use of checklists [12]–[14], crew resource management [15], [16], and most recently the analogous use of the “black box” flight recorder in the operating room setting [17], [18]. 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.

Aviation and Nuclear Energy have requirements for both quality and safety. Quality may be defined as “a degree to which a set of inherent characteristics of an object fulfills requirements” [19]. Whereas safety is defined by ICAO Annex 19 Safety Management System as the state where safety hazards are reduced and controlled to an acceptable level. The two are closely linked and share several components however they have different objectives.
1.2 Objectives and Hypothesis

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

It is 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 safety-critical industries.

1.3 Research Plan

The research plan included the following phases:

1. Two independent scoping literature reviews
2. Interviews with aviation, nuclear energy, and healthcare Subject Matter Experts (SMEs) and thematic analysis of the interview transcripts
3. A member checking exercise or focus group session with a second group of healthcare stakeholders
4. A pilot study in a healthcare unit recommended by the healthcare stakeholders.

The phases of the research plan are summarized below and described in greater detail in subsequent chapters.

1.3.1 Scoping Literature Review

Two independent scoping literature reviews were conducted to identify gaps in research with respect to the application of safety standards in healthcare delivery. The first review was completed to understand the extent of peer-reviewed research on the application of aviation and nuclear energy safety concepts in healthcare delivery. Results of this review are summarized and discussed in Chapter 2.

The second review was conducted on quality and safety management standards and practices applicable to aviation, nuclear energy, healthcare support services, and healthcare delivery services. The purpose of the second review was to understand gaps in regulations, standards, and best practices between aviation and nuclear energy and healthcare. The review identified that healthcare regulations and standards lack requirements for safety management systems and
safety processes including process control, the management of change, proactive hazard identification and closed loop risk management, fatigue management, and reliability of safety-critical tasks. The results of this review are discussed in greater detail in Chapter 3.

1.3.2 Interviews with Subject Matter Experts

Interviews with subject-matter experts in all three industries were undertaken to identify:

1) the quality and safety standards implemented and regularly practiced in each industry

2) aviation and nuclear energy quality and safety standard practices that would be applicable to healthcare delivery, and

3) healthcare processes that would benefit from implementation of proposed quality and safety standards and practices and the implementation challenges.

The healthcare questionnaire was framed around the identified safety and quality processes gaps and stakeholders were asked about safety management systems, process control, the management of change process, hazard identification and risk management, fatigue management, and reliability in healthcare delivery. These topics were the gaps identified in healthcare delivery regulations, standards, and best practices.

The main goal of interviews with healthcare stakeholders was to identify areas of healthcare delivery that have the mentioned safety practices in place or would benefit from application of such principles. Additionally, the aim was to identify the benefits and challenges of implementation of the previously identified quality and safety processes.

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.

Identified themes are discussed in greater detail in Chapter 4.

1.3.3 Member Checking

Member checking was completed through a focus group with healthcare stakeholders that differed than those interviewed initially. The purpose of this exercise was to validate the research
findings and the identified themes generated from analysis of the initial round of interviews, and to determine if the research is headed in the right direction.

The focus group took place on March 21, 2019 for approximately 2 hours and included 12 healthcare stakeholders from various disciplines. This validation method is described in greater detail in Chapter 5.

1.3.4 Pilot Study and Recommendations

A pilot study was completed in the systemic therapy unit at Princess Margaret Cancer Centre. The selection of this unit was based on the recommendations of healthcare stakeholders and because of similarities and parallels between radiation oncology and chemotherapy. Stakeholders had identified that there are certain radiation oncology units in certain hospitals that have safety management processes such as process control and the management of change process implemented. The purpose of this study and analysis was to identify areas in the systemic therapy unit, where certain aviation and nuclear energy safety principles could be applied.

The study was only an initial attempt in identifying areas where safety management system processes could be applied and resulted in a few recommendations. These are discussed further in Chapter 6.
2 Literature Review

2.1 Scoping Literature Review

2.1.1 Methodology

Application of aviation and nuclear energy safety tactics is not unknown in healthcare. To gain a better understanding of existing literature on such safety tactics, a scoping literature review was conducted using the framework developed by Arksey and O’Malley [20] and enhanced by Levac et al [21]. Based on this framework, there are five steps in a scoping literature review: (1) identify the research question; (2) identify relevant literature; (3) select studies; (4) chart the data; and (5) collate, summarize, and report the results [20].

Scopus was searched using the keywords summarized below (Table 1) to answer the research question: “What aviation and nuclear energy safety management tactics are investigated or implemented to improve patient safety in healthcare service delivery?”.

Table 1 - Summary of Keywords used for the Scoping Literature Review

<table>
<thead>
<tr>
<th>Aviation</th>
<th>(healthcare OR “health care” OR medicine OR hospital) AND aviation AND “safety management”</th>
</tr>
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<tbody>
<tr>
<td>Nuclear</td>
<td>(healthcare OR “health care” OR medicine OR hospital) AND (“nuclear power” OR “nuclear plant” OR “nuclear energy” OR “nuclear industry”) AND “safety management”</td>
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</table>

The inclusion criteria used for this scoping review were as follows: (1) articles published between 2000 to 2018; (2) articles available in English; and (3) articles that focus on application of safety management concepts, tools, frameworks, or processes commonly used in aviation and nuclear energy industries and their application to improve patient safety in healthcare service delivery settings. The exclusion criteria were as follows: (1) Articles that were focused on high-reliability organizations (HROs) and safety culture; (2) articles that were focused on safety tactics such as checklists and crew resource management, and (3) notes, editorials, letters, commentaries, and surveys. The reason for excluding articles on the use of checklists and crew
resource management was because it was realized that these tactics are commonly investigated in healthcare and are currently implemented in many healthcare institutions.

2.1.2 Results and Discussion

2.1.2.1 Overview of Scoping Review

The search of Scopus database returned a total of 292 articles. After an initial review, seventy-four articles were deemed relevant to proceed to an abstract review. Forty-one articles met the inclusion criteria based on the abstract review and therefore were selected for full-length article review. After the full-length article review, twenty-nine articles were selected to be included in the scoping review. Major themes and learnings from these articles are summarized in Appendix A and include the names of the authors, year of publication, title, applicable healthcare area, and the safety tactics discussed. A graphical representation of the extent of research into each theme is presented in Figure 1 and a summary of major themes in presented in Table 2.

Figure 1 - Safety Tactics Investigated in Healthcare

<table>
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<tr>
<th>Safety Tactics Investigated in Healthcare</th>
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<tr>
<td>Other</td>
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<tr>
<td>Human Factors</td>
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<tr>
<td>Incident Reporting / Investigations</td>
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<td>Risk Assessment</td>
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<tr>
<td>Hazard Identification</td>
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<td>Safety Management System</td>
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0 5 10 15 20 25 30 35 40 45
Table 2 - Major Themes on Safety Tactics Adopted from Aviation and Nuclear Energy for Implementation in Healthcare

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Safety Management System</th>
<th>Hazard Identification</th>
<th>Risk Assessment</th>
<th>Incident Reporting / Investigations</th>
<th>Human Factors</th>
<th>Other</th>
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<td>Hudson et al.</td>
<td>2012</td>
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<td>Wreathall et al.</td>
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<td>Davies et al.</td>
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<td>Bennett</td>
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2.1.2.2 Identified Gaps in Peer-Reviewed Literature

As summarized in Figure 1 and Table 2, 10 articles (40%) focused on the development of frameworks or application of lessons learned related to hazard identification [22]–[31] and 10 articles (40%) focused on risk management which included risk assessment [26]–[28], [30], [32]–[36] and developing robust risk control strategies [36]. Some examples of hazard identification techniques that were discussed were near-miss reporting [22], [23], [31], peer-to-peer assessments [24], safety audits [26], and in-situ simulation [28], [29]. Another method discussed is the use of a risk identification framework which is a system-based approach to risk identification and includes components such as system mapping and thorough system analysis to identify sources and nature of hazards, followed by risk identification and presentation [25]. Similarly, Donahue et al. have also proposed and investigated a framework that helps create a system safety architecture for healthcare processes/units through defining all operational systems and subsystems followed by completion of a safety assessment and risk-prioritization [30]. With respect to risk management, only 2 articles [31], [36] out of the 10 discussed implementation of strong risk mitigation strategies in response to adverse events. Examples of risk assessment techniques proposed are probability risk assessment (PRA) [32] and sociotechnical-probability risk assessment (ST-PRA) which requires consideration of human actions and performance to determine the probability of occurrence for an error or event [33].

32% of the articles discussed incident reporting and investigations in aviation [31], [34], [35], [37]–[41]. These topics included importance of non-punitive reporting and investigations of near-misses and incidents. Several articles have recommended incident investigations by a committee within the hospital (experience feedback committee) [37], a national clinical investigation board [38] or a central safety investigation agency [40] that is independent of the hospital, similar to the National Transportation Safety Board (NTSB) in aviation. Another recommendation is to establish a safety investigation board similar to that observed in aviation (Commercial Aviation Safety Team (CAST)) [36]. CAST includes two separate teams; one team investigates aviation incidents and accidents, determines the root-cause and events that lead to the event, conduct risk analysis and recommends several risk mitigation strategies [36]. The first team also evaluates the effectiveness of each mitigation strategy [36]. These mitigation strategies then proceed to the second team who is in charge of planning and resourcing for implementation of the proposed risk control strategies [36]. Pham et al. has proposed a similar model for incident
investigations, RCA, and risk mitigation strategy development and implementation for healthcare. The proposed RCA framework includes analysis of the event that happened and why it happened, identifying and prioritizing the factors that caused harm, and evaluating the probability that the identified factors would cause harm in the future [35]. Following the identification of the root-cause and the contributing factors, the investigation team recommends several risk controls and ranks them based on their level of effectiveness [35]. The model also requires a separate implementation team to develop plans for implementation of proposed risk controls [35].

24% of the articles discussed the importance of human factors, error management, and error proofing processes [22], [27], [31], [39], [42], [43]. Some articles proposed frameworks or methodologies to analyze processes and identify areas where there is a mismatch between humans and their environment and considering factors such as human use and interaction with technology, procedures, and other elements of the system [27], [31], [39]. A few articles also propose standardization of procedures, the work environment layout, and design on medical devices [22], [31], [39] as a means of reducing or eliminating probability of human errors.

12% discussed other safety tactics such as use of sterile cockpit concept [34], [39], standardized communication [22], and peer reviews and safety huddles [22]. Sterile cockpit is when aircraft pilots are provided with an environment where there are no interruptions during critical phases of a flight, such as during take-off and landing [34], [39]. It is suggested that healthcare staff would benefit from no interruption zones in hospitals during critical tasks such as medication administration [39].

4 articles (16%) discussed or made references to aviation’s safety management system [27], [41], [44], [45]. Only one of these articles presented an SMS framework for healthcare. Additionally, none of these articles discussed the aviation safety management system in detail or analyzed any of requirements or components.

2.2 Regulations, Standards, and Guidelines Literature Review

2.2.1 Methodology

A review of literature was conducted to explore aviation, nuclear energy, and healthcare safety and quality regulations and/or standards and to answer the research question: “What safety and
quality regulations and/or standards are implemented in safety-critical industries such as Aviation and Nuclear Energy?"

Three separate web searches were completed using keywords aviation safety standards, nuclear safety standards, and healthcare safety standards. Each search returned thousands of results, however the review was limited to the first 5 pages or the first 100 results.

The objectives of this literature review were as follows (1) to identify organizations that establish and enforce regulations relevant to aviation, nuclear energy, and healthcare; (2) to identify organizations that develop standards for aviation, nuclear energy, and healthcare; and (3) to identify safety and quality regulations, standards, and guidelines relevant to aviation, nuclear energy, and healthcare.

2.2.2 Results and Discussion

2.2.2.1 Overview of Regulations and Standards Literature Review

One international organization and several Canadian, American, and European organizations were identified as those that regulate aviation industry and publish regulations, standards, and guidelines on aviation operational safety and quality.

Similar to aviation, one international organization and several Canadian and American organizations were identified as those that regulate the nuclear industry and use of nuclear materials. These organizations publish standards, regulations, and best practice guidelines on safety and peaceful use of nuclear materials and nuclear energy. Safety and quality regulations, standards, and guidelines were identified through hand searching of these organizations’ websites. A list of relevant publications is presented in Appendix B and Appendix C.

2.2.2.2 Aviation Regulations, Standards, Guidelines and Regulatory Framework

International Civil Aviation Organization (ICAO)

ICAO is a United Nations (UN) agency which collaborates with 193 member States (countries) and industry partners to develop international civil aviation Standards and Recommended Practices (SARPs) specifying the minimum requirements relevant to aviation operations, safety, and maintenance [46]–[55]. ICAO member states use the SARPs to ensure harmonized civil
aviation operations and regulations. ICAO also publishes guidelines or manuals [52], [53] to assist the member States with the implementation of SARPs and requires that its member states establish a regulatory body to oversee aviation operations and to enforce policies.

Member State Regulators

Member States regulators (i.e. Transport Canada, U.S. Federal Aviation Administration (FAA), and European Union Aviation Safety Agency (EASA) etc.) develop regulations that require civil aviation organizations to implement safety policies, procedures, processes, and systems based on ICAO SARPs. The member state regulators or government agencies also publish advisories and guidance documents to assist civil aviation organizations in implementing the mandated policies, procedures, processes and systems. For the purposes of this research, the literature review was limited to the regulations, advisories, and guidance documents developed by Transport Canada and the FAA.

Transport Canada is the Canadian aviation regulatory body that issues and enforces Canadian Aviation Regulations (CARs) [56] to ensure safety for all forms of transportation in Canada, including civil aviation. Transport Canada also develops guidance documents [57]–[61] and oversees adherence to CARs by issuing certificates or licenses for operations and conducting audits and surveillance.

Investigations of aviation accidents and incidents is performed by an independent agency known as Transportation Safety Board (TSB) of Canada which is established under Canadian Transportation Accident Investigation and Safety Board Act [62]. TSB investigates transportation occurrences including aviation occurrences that took place in or over Canada or any place that is under the Canadian air traffic control, and in or over any place if Canada is requested to investigate or if the incident has involved a Canadian aircraft [62]. The objectives of TSB are to (1) independently investigate selected transportation occurrences to identify their causes and contributing factors, (2) identify safety deficiencies, (3) make recommendations to eliminate or reduce identified safety deficiencies, and (4) report publicly on the investigations and their results [62]. The act also has an associated regulation with requirements for mandatory reporting of aviation occurrences involving death, serious injury, and damage to the aircraft, as well as voluntary reporting of other aviation occurrences that do not fall under the mandatory reporting category [63].
Similar to Transport Canada, the FAA or the U.S. aviation regulatory body, develops and enforces Federal Aviation Regulations (FARs) and minimum standards [64], [65] and advisory circulars (guidance documents) [65] for manufacturing, operation, and maintenance of aircrafts.

The investigation of aviation accidents and incidents in the United States is also performed by an independent government agency, called the National Transportation Safety Agency (NTSB). The mandate of NTSB is to (1) remain objective and independent (2) conduct objective and precise investigations (3) promote safety recommendations and (4) assist victims of transportation accidents and their families [66].

A regulatory framework for civil aviation is presented in Figure 2.
Figure 2 - Civil Aviation Regulatory Framework

International Civil Aviation Organization (ICAO)

Sets standards and recommended practices and governs global civil aviation

193 Member States

Canada

Aeronautics Act
- Transport Canada (TC)
  - Enforces the Aeronautics Act
  - Develops regulations
  - Oversees Canadian aviation operations
  - Issues certificates to aviation organizations

Canadian Transportation Accident Investigation and Safety Board Act

Regulation: Canadian Aviation Regulations (CARs)
Guidance Documents: Advisory Circulars (ACs)

Aviation Organizations

United States

Aeronautics and Space Act
- Transportation Safety Board of Canada (TSB)
  - Conducts independent investigations of aviation incidents/accidents

Federal Aviation Administration (FAA)
- National Transportation Safety Board (NTSB)
  - Conducts independent investigations of aviation incidents/accidents

- Issues certificates to aviation organizations

Regulation: Federal Aviation Regulations (FARs)
Guidance Documents: Advisory Circulars (ACs)

Aviation Organizations

European Union

European Union Aviation Safety Agency (EASA)
- Regulates civil aviation in its member States
- Issues certificates/licenses to aviation organizations
- Conducts investigations into aviation incidents

Civil Aviation Authorities (CAAs)
- Regulate civil aviation in other parts of the world

Other Member States
2.2.2.3 Nuclear Energy Regulations, Standards, Guidelines and Regulatory Framework

**International Atomic Energy Agency (IAEA)**

Similar to ICAO, the International Atomic Energy Agency (IAEA) publishes nuclear standards, requirements and recommendations to harmonize nuclear safety globally. IAEA has 171 member States whose regulatory bodies or other national organizations overseeing nuclear safety are the main users of IAEA standards. Examples of such regulatory bodies are the Canadian Nuclear Safety Commission (CNSC), the United States Nuclear Regulatory Commission (NRC), and the United States Department of Energy (DOE). The relevant safety and quality standards and requirements published by IAEA [67]–[78] are listed in Appendix C.

**Canadian Nuclear Safety Commission (CNSC)**

Canadian Nuclear Safety Commission (CNSC) is the Canadian regulator that issues laws, regulations, and regulatory documents and oversees the development, production, and use of nuclear energy in Canada per the Nuclear Safety and Control Act (NSCA) [79]. The NSCA includes several regulations [80], [81] and regulatory documents [82]–[88]. Regulatory documents are similar to guidelines and inform nuclear organizations on how to implement the mandated safety systems and processes. The relevant publications that were reviewed for this research are listed in Appendix C.

**Canadian Standards Association (CSA) Group**

The Canadian Standards Association (CSA) group or the CSA group is a global organization that develops standards for various industries and operations including Nuclear Energy and Healthcare. The CNSC regulatory documents refer to several CSA standards as the standard or best practice that nuclear energy organizations should utilize to successfully implement the mandated safety and management systems, processes, and procedures. The relevant nuclear energy CSA standards [89]–[94] are summarized in Appendix C. The relevant healthcare standards [95]–[98] are listed in Appendix D.
Nuclear Regulatory Commission (NRC)

The equivalent of CNCS in the United States is the U.S. Nuclear Regulatory Commission (NRC) however, the NRC oversees nuclear and nuclear material safety, licensing of new nuclear power plants, license renewal for existing nuclear power plants and materials, and nuclear waste management. One relevant publication by the NRC on fatigue management and fitness for duty [99] has been identified and is listed in Appendix C.

Department of Energy (DOE)

Department of Energy (DOE) is the organization that oversees the operations of all energy manufacturing plants, including nuclear power plants, in the United States. Two publications on human performance and human reliability [100], [101] have been identified and are listed in Appendix C.

The regulatory framework for nuclear energy is presented in Figure 3.
Figure 3 - Nuclear Energy Regulatory Framework

International Atomic Energy Agency (IAEA)

Sets standards for safety and governs the use of nuclear energy globally

171 Member States

Canada
Nuclear Control and Safety Act

- Develops regulations
- Oversees Canadian nuclear facilities operation and use
- Issues licenses to nuclear facilities

Guidance Documents:
Regulatory Documents (REGDOC)

United States
Energy Reorganization Act

United States
Department of Energy Organization Act

- Nuclear Regulatory Commission (NRC)
  - Regulates use of radioactive materials in the United States
  - Administers licensing of nuclear reactors

- Department of Energy (DOE)
  - Ensures safe and secure energy production, including nuclear energy

Other Member States

National Regulatory Agencies
- Regulate use of nuclear material
2.2.2.4 Healthcare Regulations, Standards, Guidelines and Regulatory Framework

**Health Canada**

Health Canada (HC) is a government agency that creates and enforces regulations with impact on health and safety of Canadians [102]. Similar to Transport Canada and the Canadian Nuclear Safety Commission, HC also develops standards and guidelines to facilitate interpretation of legislations and regulations. One relevant legislation or Act administered by HC is the Food and Drugs Act which applies to all food, drugs, cosmetics, and medical devices that are sold in Canada [103]. Although this act does not include any regulations for the delivery of healthcare, there were several regulations [104], [105] and associated standards and/or guidelines [106], [107] that were reviewed for the purposes of this research. These are listed in Appendix D.

**Canadian Patient Safety Institute (CPSI)**

There were no regulations or standards administered and enforced by HC related to healthcare service delivery. However, HC has created and appointed the Canadian Patient Safety Institute (CPSI) to coordinate building a safer healthcare system and provide leadership in this area [108].

CPSI is not a regulating body however, they provide tools and resources, education, interventions and programs with respect to patient safety and recommended practices and processes [108]. Examples of tools and resources offered by CPSI are checklists, framework, toolkits, and guides. CPSI publication [109] reviewed for the purposes of this thesis project is listed in Appendix D.

**The Government of Ontario and Health Quality Ontario (HQO)**

The government of Ontario has published two acts [110], [111] and several regulations for public hospitals in Ontario. Only two of these regulations [112], [113] were deemed relevant to this research and are included in this literature review. The government of Ontario also established an independent agency known as Health Quality Ontario (HQO) whose mandate is to report on the performance of the healthcare system to the public, organizations, healthcare providers, and the government [114]. HQO also publishes standards on best practices with respect to specific clinical processes. However, these standards were not included as they are very specific and
unique to certain clinical processes and applicable at the unit level in contrast to SMS standards which are applicable at the organizational level. However, these standards were reviewed to obtain a better understanding of standardization of clinical care in Ontario hospitals.

Health Standards Organization (HSO)

HSO is a new organization with focus on “developing standards, assessment programs, and other methodologies to enable health and social service providers around the world to move the needle on quality while doing what they do best: saving and improving lives” [115]. HSO is an affiliate of Accreditation Canada, the hospital accrediting body that is voluntary. HSO develops and maintains more than 100 standards for healthcare and social services. At the time of this writing, the standards were not widely known or used. They were not reviewed for the purposes of this study.

International Organization for Standardization (ISO)

ISO is a non-governmental international organization operating independently to create standards for voluntary adoption by member countries. ISO is known for their quality management standards which are implemented in many manufacturing industries to ensure customer satisfaction and quality products. A few ISO standards [19], [116]–[118] applicable to healthcare were identified and these are listed in Appendix D.

The regulatory framework for Canadian healthcare is presented in Figure 4.
3 Gaps in Regulations, Standards, and Guidelines

3.1 Safety Management Systems

3.1.1 Aviation

Based on the literature review of aviation and nuclear energy regulations and standards, it was identified that aviation and nuclear energy organizations are required to implement both a Safety Management System (SMS) and a Quality Management System (QMS), or an integrated management system which is the case in nuclear energy [48], [52], [56], [67], [89], [119].

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” [82]. Aviation defines safety management system (SMS) as “a systematic approach to managing safety, including the necessary organizational structure, accountabilities, policies and procedures” [48]. A quality management system (QMS) is a “a set of interrelated or interacting elements of an organization to establish quality policies, quality objectives, and processes to achieve those objectives” [19].

SMS and QMS are complementary and may seem similar but only have some elements in common. Common elements are audits, performance monitoring and continuous improvement of the management system [120]. However, an SMS is inherently risk-based and differs from a QMS [120]. 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 [52], [119]. In contrast, the QMS is concerned with the quality of a product or a service, customer satisfaction, and focuses on the consistent delivery of products and services that meet relevant specifications [52], [119].

The review of regulations, standards, and guidelines in aviation, nuclear energy and healthcare service delivery showed that all three industries require the implementation of quality management systems or a QMS. However, only aviation and nuclear energy have explicit requirements for implementation of a safety management system.
As explained previously, ICAO sets forth standards and recommended practices (SARPs) to harmonize member States safety management activities and processes. As part of this proactive approach to safety, ICAO recommends that member States implement a State Safety Programme (SSP) which is “An integrated set of regulations and activities aimed at improving safety” [46], [48], [50]–[52]. There are several organizations, under the authority of the States, that provide aviation services. Examples of such organizations are: (1) authorized training organizations exposed to safety risks related to aircraft operations (2) authorized operators of aeroplanes or helicopters conducting international commercial air transport and their respective maintenance organizations (3) authorized international general aviation operators of large or turbojet aeroplanes (4) certified organizations that design or manufacture aircrafts (5) certified air traffic services (ATS) providers; and (6) operators of certified aerodromes.

Per ICAO’s requirements, the States are required to have these aviation organizations implement a Safety Management System (SMS). ICAO Annex 19 Safety Management presents ICAO’s proposed framework for an SMS which includes the four components and twelve elements presented in Figure 5.
In accordance to ICAO SARPs in Annex 19 Safety Management, member States such as Canada and the United States and their respective aviation regulators, require all aviation organizations (certified or applying for certification) to establish and maintain an SMS [56], [64]. As an example, Transport Canada requires Canadian aviation organizations to implement an SMS per the Canadian Aviation Regulations (CARs) SOR/96-433 [56]. Similar to Transport Canada, the FAA requires American aviation organizations to implement an SMS per the Federal Aviation Regulations (FARs) [64].

Although the specific requirements for a Safety Management System may differ between States, all safety management systems have the same basic components in common. These minimum requirements are described briefly in the next paragraph.

1. Safety Policy and Objectives

ICAO recommends that a safety management system includes a safety policy and safety objectives established by aviation organizations. The safety policy shall:

- be signed by the accountable executive, documented and communicated throughout the organization, and regularly reviewed [46], [48], [50], [52], [56], [64]
- demonstrate an aviation organization’s commitment to safety and include a statement on allocation of resources for the implementation of the safety policy and the safety management system [46], [48], [50], [52], [64]
include procedures for reporting of safety concerns, hazards, incidents, occurrences, and accidents by employees [46], [48], [50], [52], [56], [64]; and state behavior that is considered unacceptable and conditions for disciplinary action [46], [48], [50], [52], [64]

Aviation organizations are required to:

- define safety accountabilities, responsibilities, and authorities for the accountable executive, management, and employees [46], [48], [50], [52], [64]. As an example, accountable executive is the final authority for operations conducted by the aviation organization and is ultimately responsible and accountable for implementation and maintenance of the SMS, and the operational safety performance of the organization [48], [64].

- identify management levels authorized to make decisions with respect to safety risk acceptance or tolerance [48], [64]. Safety management personnel, identified and designated by the accountable executive, are responsible for implementation and maintenance of the SMS throughout the organization [48], [64].

2. Safety Risk Management (Hazard identification and risk assessment and mitigation)

Safety risk management involves hazard identification and safety risk assessment and mitigation[48], [64]. It shall be applied to [64]:

- New systems being implemented
- Existing systems going under modifications
- Operational procedures development
- Identification of hazards and ineffective risk mitigations

ICAO requires aviation organizations to have processes in place to identify hazards associated with aviation operations and services [46], [48], [50], [52]. Such processes may include a combination of proactive, predictive, and reactive data collection [46], [48], [50], [52].
The FAA requires aviation organizations to conduct system analysis to identify hazards that would negatively impact safety performance of an organization [64]. System analysis involves defining function and purpose of a system, the operating environment, an outline of the system’s processes and procedures, and required resources, with respect to equipment, personnel, and facilities, to operate the system [64]. All identified hazards need to be assessed for safety risks [48], [52], [56], [64]. Aviation organizations are mandated to have processes in place for risk analysis and assessment and determination of acceptable risk or risk tolerance [48], [52], [56], [64]. Organizations are also required to implement processes to define safety risk control and determine whether the risk will be acceptable/tolerable with the proposed risk control applied, prior to implementing a proposed risk control [48], [52], [56], [64].

3. Safety Assurance (performance monitoring and assessment, management of change, and continuous improvement)

Safety assurance includes monitoring and measurement of safety performance, management of change, and continuous improvement of the SMS [46], [48], [50], [52], [56], [64]. ICAO requires aviation organizations to have means in place for verification of safety performance and validation of the effectiveness of safety risk controls [46], [48], [50], [52]. To comply with this requirement, Transport Canada requires aviation organizations to have means of evaluating attainment of established safety performance goals [56]. The FAA requires that organizations create and maintain processes to collect and analyze data pertaining to operations and services and monitor the safety performance of their organizations [64]. Processes shall also be in place to address safety performance deficiencies identified during the safety performance assessment [64]. Ineffective risk controls, changes in the operational processes, the operational environment, and those that impact aviation safety risks need to be addressed and assessed through the safety risk management process [48], [64]. In addition to monitoring and measurement of safety performance, aviation organizations are also required to monitor, measure, assess, and improve the performance of the SMS [46], [48], [50], [52], [56], [64].
4. Safety Promotion (training and communication)

As part of safety promotion, aviation organizations are required to provide training to all personnel who have duties related to the SMS operation and performance [46], [48], [50], [52], [56], [64]. Through safety communications, aviation organizations must ensure that employees are aware of SMS policies, procedures, and tools, hazards relevant to the employees and their responsibilities, safety actions and their justification, and revised or new safety procedures and the justification for their revision or implementation [46], [48], [50], [52], [56], [64]. Records of all training and safety communications must be maintained for as long as possible [64].

The SMS, including its processes, procedures, policies, objectives, outcomes of safety risk management and the safety assurance processes need to be documented and maintained [46], [48], [50], [52], [64].

While ICAO sets the minimum requirements for aviation safety management systems, State regulators may require implementation of an SMS that includes components and elements additional to those required or recommended by ICAO. For example, Transport Canada requires Canadian aviation organizations to have a quality assurance program as a component of their SMS [56].

3.1.2 Nuclear Energy

Similar to ICAO, the International Atomic Energy Agency (IAEA) publishes nuclear standards on safety principles, requirements and recommendations to harmonize nuclear safety globally.

The IAEA has published requirements in the form of a standard for a governmental, legal, and regulatory framework for nuclear safety [68]. Within this standard are the requirements for each State to:

- Establish and maintain a governmental, legal, and regulatory framework for safety which includes licensing and the rationale for license approval by a regulatory body and periodic inspection and assessment of nuclear facility operations [68].

- Establish and maintain a regulatory body that has independence in safety-related decision making and whose main function is to control nuclear facilities and activities [68].
The established regulatory body is required to liaise with other authorized agencies and advisory bodies and ensure consistent and stable regulation of nuclear facilities and activities in accordance with approved policies and procedures with reasonable justification for the decisions [68]. IAEA also requires States to enhance global safety through participation in international peer reviews and sharing of lessons learned and operating experience [68].

In accordance with IAEA requirements for a regulatory body, in Canada, the CNSC issues licenses to nuclear facilities to prepare, construct, operate, and decommission a nuclear site [80], [121]. One of the licensing requirements is to have a management system which includes safety culture promotion and support and a human performance management program which includes means of ensuring workers’ fitness for duty [80]. The CNSC publishes regulatory documents to guide the applicants in preparing the required documentation, proposals, and processes [121].

Both aviation and nuclear energy require organizations to take a management system approach to safety. The difference between the two industries is that while aviation specifically requires a safety management system to be implemented, nuclear energy requires implementation of an integrated management system. Nuclear management system integrates all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality, security, health, and environment; and so that safety is not compromised by the need to meet other requirements or demands [68], [69].

The nuclear integrated management system includes the requirements, components, and elements listed below. These requirements are similar to those observed in aviation SMS.

1. **Safety policy and objectives**: the management system shall include a safety policy; requirements shall be defined and objectives relevant to meeting such requirements shall be established [69], [82], [89].

2. **Accountabilities, responsibilities, and authority**: management shall define the organizational structure, accountabilities, responsibilities, and authorities, and behavioural expectations within the organization [69], [82], [89].
3. **Resources:** required resources to carry out the business plan shall be determined [69], [82], [89].

4. **Performance Monitoring:** targets shall be set and the organization shall monitor and measure the degree to which targets and requirements are met. A strong safety culture shall be fostered with regular measurement and assessment of safety performance [69], [82], [89].

5. **Problem identification, resolution, and resolution effectiveness verification:** Problems shall be immediately identified, documented, evaluated, analyzed for their root-cause, and resolved. Actions taken to resolve the problems need to be verified for their effectiveness [69], [82], [89].

6. **Change Control:** changes that impact safety need to be identified, justified, reviewed and approved by stakeholders prior to being implemented, and reviewed for effectiveness [69], [82], [89].

7. **Work Planning, Control and Verification:** work shall be carried out per controlled documents, processes and practices; critical characteristics of the work to be performed need to be identified and verified by verification workers [69], [82], [89].

8. **Performance Assessment and Continuous Improvement:** management shall ensure that self-assessments and independent assessments are completed to ensure compliance with the management system requirements, to measure attainment of objectives and results, and to identify areas that require improvement [69], [82], [89].

9. **Training:** workers shall be provided with training to ensure they are competent in performing their duties [69], [89].

10. **Communication:** effective communication shall be established within the organization and workers shall be made aware of the importance of their roles in enabling the organization to meet its objectives and targets [69], [82], [89].
11. **Management system documentation**: the management system and its processes shall be documented and maintained; information and documents shall be readily available to those who require them [69], [89].

3.1.3 **Healthcare**

Healthcare is divided into two sectors: (1) healthcare support services and (2) healthcare service delivery. Healthcare support services are those that are not directly related to the delivery of care such as operations of the blood banks, medical laboratories, transplantation processes, and manufacturing of medical devices. Healthcare service delivery is the direct delivery of care in a hospital setting and is related to the operations and processes that take place in a clinical setting such as chemotherapy, radiation therapy, and surgery.

Review of regulations, standards, and guidelines for some **healthcare support services** showed that there are no explicit requirements within these documents for implementation of a safety management system, similar to the SMS and the integrated management system that are mandated in aviation and nuclear energy industries. However, there are requirements for implementation of a Quality Management System (QMS), a quality assurance system or certain quality processes in healthcare support services organizations [95]–[97], [104]–[107], [116], [122]–[124].

Canada’s blood products regulations, guidelines, and the CSA standard require **blood product establishments** to have a quality management system independent of other functional units [95], [104], [106], [122]. Per the regulatory requirements by Health Canada, a condition for registration or licensing of blood product establishments is the presence of an effective quality management system [104]. Similarly the cell, tissue, and organ transplantation establishments shall also be registered in accordance with the Health Canada regulatory requirements [105]. As per the regulations, guidelines, and the CSA standard, establishments shall have a quality assurance system in place [96], [105], [107], [123].

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 [97], [116], [124].
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) [98], [117]. Both these standards lack safety management system principles and components and are solely focused on quality and implementation of a quality management system. There are no requirements specified within healthcare support services or healthcare delivery regulations, standards, or best practices for implementation of a safety management system.

Some of the requirements for the quality management system are similar to those of other management systems, such as the SMS and nuclear energy’s integrated management system. Below are some of the common requirements between a QMS and an SMS.

1. **Policy:** A quality policy shall be developed [95], [97], [98], [106] and authorities and responsibilities of individuals shall be clearly defined [95]–[98], [106], [117].

2. **Provision of Resources:** There shall be a sufficient number of qualified and competent staff to successfully carry out their assigned duties and responsibilities [95], [97], [98], [105], [117].

3. **Control Processes:** The facility shall have in place, control processes such as validated operating procedures or activities [95], [96], [98], [104]–[106], [117], change control [95], [98], [104], [106], and audits [95]–[98], [104]–[106], [117].

4. **Corrective Action and Preventative Measures:** Errors, accidents, and deviations from normal operating procedures shall be identified, investigated, and evaluated [95]–[98], [104], [106], [117]. Corrective actions shall be implemented [95]–[98], [104], [106], [117]. Effectiveness of the corrective actions in resolving the identified problems shall be evaluated [95], [97], [106], [117].

5. **Continuous Improvement:** Periodic review of the management system to validate its continuous effectiveness and applicability [95]–[98], [104], [106], [117].

6. **Training:** There shall be documented training programs for all personnel involved in establishment and management of a QMS [95]–[98], [104]–[106], [117]; Effectiveness of the training program shall be validated at regular intervals [95], [106]; There shall be
training proficiency tests and competency assessments to evaluate knowledge of procedures [95]–[98], [104]–[106], [117].

Although both management systems are similar in terminology used to describe their specific components and elements, QMS and SMS are fundamentally different. A QMS ensures that processes are standardized with no variation and that customers are satisfied. In that respect, a QMS is not concerned with safety hazards, safety risks, or safety risk management. Terminology such as “safety hazards”, “safety risks”, “safety risk management”, “safety risk control”, and “safety performance” are largely absent from QMS or quality system standards. A list of SMS processes, observed in aviation and nuclear energy management system regulations, standards, and guidelines, that are not included in healthcare QMS or quality system regulations, standards, or guidelines are as follows:

1. **Design verification and validation** - Including verification and validation of the design output to the design input specifications and verification and validation of the human factors design. Reliability shall be a design input.

2. **Safety hazard identification** - Including environmental factors and design of equipment, processes, procedures and work schedules that would have an impact on safety such that if unidentified or unaddressed these will lead to a near-miss, incident, accident, or error. This includes taking into account modifications or changes to regulatory requirements, safety-critical equipment, processes, and procedures, human fatigue and human performance.

3. **Safety Risk Management** - Includes assessment and evaluation of safety risks using effective and known safety risk assessment methods taking into account probability and consequences of occurrence and the tolerability of the organization and its processes to absorb or recover from such safety risks. This also includes developing safety risk controls that are appropriate based on the safety risk assessment and should include a combination of administrative and engineering controls.

4. **Safety Assurance** - Includes monitoring and evaluating (1) the performance of implemented safety risk controls to ensure their effectiveness and (2) the performance of the SMS with respect to safety performance indicators.
3.2 Control Processes

3.2.1 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.” [106]. Process control may be achieved through (1) standard operating procedures and the processes of (2) verification and (3) validation.

Verification (Figure 6) is defined as “a process through which new development is evaluated against its design specification.” [117].

Validation (Figure 6) is defined as “a process through which a new development is tested under controlled conditions to see if it meets the performance requirements” [117].

**Figure 6 - Verification and Validation in Process Control**
3.2.1.1 Aviation

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 [50]. This may be accomplished by conducting periodic emergency drill exercises where the designed plan is executed and areas of improvement are identified [50]. Other processes and safety tools that require validation in aviation are operating procedures and practices, checklists used in these processes and practices under normal operating conditions, and personnel training to ensure that the provided training is effective [52].

Verification is also required under the safety assurance component of the SMS. Aviation organizations are expected to establish safety performance indicators / targets / objectives to validate the effectiveness of implemented safety risk controls by verifying the organizational safety performance against these established criteria [46], [48], [50], [52], [56], [64]. Safety performance and mitigation effectiveness verification is also discussed in Chapter 5.

3.2.1.2 Nuclear Energy

Validation and verification in nuclear energy are applied to design engineering [67] and human factors engineering [73], [86], [90] by evaluating the design against requirements or specifications. More specifically, verification and validation are required for plant design [67], [71], quality of facilities and activities [67], equipment [67], design tools [71], and design inputs/outputs [71] by independent groups or individuals who were not involved in the design engineering work [71], [89]. Verification and validation must be completed for operating procedures and test procedures, in the manner in which the procedures are to be used, to verify their technical accuracy and validate their usability [72], [75]. Iterative validation and verification should also be completed during the design and planning stage and prior to implementation, for advanced and detailed design and as part of the evaluation process for human-machine interface (HMI) with respect to human factors and human performance [73], [86], [90]. Nuclear industry also requires use of simulators to verify plant and operational features relevant to human factors and to validate that appropriate actions by the operator are correctly identified and performed [71].
Nuclear Safety Assessments are also subject to verification by independent groups or individuals who were not involved and did not perform the initial safety assessments [70].

3.2.1.3 Healthcare

Regulations and standards for blood processing establishments, require that these organizations have process control as an element of their Quality Management System [95], [104]. Per these requirements, the operating procedures for blood processing activities shall be validated to ensure the safety of products and services [95]. Comprehensiveness of the validation is dependent on the criticality of the activities. Additional process control procedures include (1) change control; (2) proficiency testing program; (3) quality control; (4) raw material control and/or supplier qualification; (5) internal audits or inspection program; and (6) identification and traceability of critical elements (materials used, products, or documentation) [95].

Similarly, the standard for cells, tissues, and organs transplantation specifies that procedures, processes, equipment, and analytical methods shall be validated either in-house or by the supplier (if procured from a supplier) prior to implementation. All processes shall be revalidated following significant changes. [96]

Medical laboratories are also recommended to have validated testing methods, processes, procedures and computer software [97], [116].

Requirements for process control are also evident in healthcare delivery standards. The quality management system standard for healthcare delivery [98] has a requirement for process control which requires that processes and standard operating procedures that impact quality and safety be updated at planned intervals. The ISO 9001:2015 quality management system standard for healthcare [117] also has requirements for systematically defining and managing clinical processes, their interdependencies, and interactions. This ISO quality management standard is the only healthcare delivery standard reviewed that has requirements for defining user requirements, design specifications, and expected results, and implementing validation and verification processes to ensure expected results satisfy the user requirements and design inputs [117]. These requirements are as follows: (1) documented characteristics of products, services, or activities; (2) use of suitable infrastructure and environment for the operation of processes; (3) implementation of actions to prevent human error; (4) documented expected results/outputs to be
achieved; (5) implementation of monitoring and measurement activities at appropriate stages/phases to verify that criteria for control of processes or outputs, and acceptance criteria for product and services, have been met; and (6) validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision. It must be noted that although the quality management standard for healthcare [117] includes process control requirements, there are no accompanying guidance documents to enable healthcare organizations with implementation of the listed requirements. Unlike aviation and nuclear energy where extensive resources are available to organizations to facilitate implementation of control processes, healthcare delivery standards have no accompanying guidance documents or manuals.

3.2.2 Management of Change / Change Control

Management of Change (MOC) is a best practice used to ensure that safety, health and environmental risks are controlled when a company subject to major accident 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 when it was determined that several catastrophic incidents were a result of mismanaged changes to processes or equipment. Since then, the MOC process is required by law. [125], [126]

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 [127]. Change control can be defined as a structured documented method of revising a policy, process, or procedure and its associated systems [95]. The change control process and the MOC process include the steps outlined in Figure 7.
3.2.2.1 Aviation

Management of change is a component of safety assurance in aviation. As part of the SMS requirement, changes that could have an impact on safety of aviation products or services are identified, assessed, and controlled in a systemic manner [46], [48], [50], [52], [64].

Any change including organizational expansion, downsizing, and changes to existing systems and equipment, policies, procedures, and regulations may introduce new hazards into the aviation systems. Proposed changes need to be systematically evaluated and assessed, hazards associated with the changes need to be identified, and safety risk controls need to be implemented and evaluated following the implementation for their effectiveness. [52]

Management of safety risks associated with changes should take into consideration (1) Criticality of system and activities, (2) Stability of systems and operational environment, and (3) Past performance [52].

Aviation’s management of change process requires periodic review of system descriptions followed by hazard identification and risk assessment to ensure validity of identified hazards and safety risks [52].
3.2.2.2 Nuclear Energy

Similar to aviation, nuclear energy’s management system requires changes to be identified, justified, reviewed by relevant stakeholders/individuals knowledgeable in the field, approved, implemented, and monitored for effectiveness. Nuclear energy refers to this process as ‘change control’. [89]

Nuclear organizations are mandated to conduct periodic safety reviews and safety assessments of their facilities and activities partially or in full [67], [70]. Following these reviews and due to regulation changes, lessons learned from other nuclear facilities, near-miss reports, and incidents/accident analysis, nuclear organizations may need to change the design of their equipment and processes. All changes to a nuclear power plant facilities and activities, temporary or permanent, must be evaluated and assessed for their safety significance and impact and shall not negatively affect safe operation of the nuclear facility. Changes may have a significant impact on safety of nuclear facility and activities or may not pose any safety risks. Changes that have significant safety impact should be reported to the regulatory body. Non-safety relevant changes are recommended to be documented and made available to the regulatory body, if required, with appropriate assessments that demonstrate these changes have no impact on safety. Modifications to the design of the nuclear power plant such as systems, equipment, and components need to be verified and validated to meet the original design intent. [74]

Any modifications to the operating procedures should also be verified and validated prior to use and operator training shall be provided [74].

3.2.2.3 Healthcare

Planning for and anticipating changes are referenced within a few healthcare support services regulations, standards, and guidelines. In the blood and blood components regulation, standard, and guidelines, there are requirements for implementation of a change control system as an element of process control [95], [104], [106], [122]. The change control system is intended to (1) capture, review, approve, and control all processes; (2) document, evaluate, approve, and manage changes to facilities, equipment, supplies, and processes; and (3) ensure revalidation of facilities, equipment, supplies, and processes following significant changes [106].
Similarly the guidance document for transplantation activities specifies that changes to facilities, equipment, materials, and processes must be documented and approved prior to implementation [107].

The 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 [98]. Similarly, the European standard for healthcare clinical processes requires organizations to plan for changes in a controlled manner and consider the consequences of unintended changes to mitigate adverse effects [117]. Additionally, this standard specifies that any changes to product or service requirements are to be documented and communicated with relevant stakeholders [117].

There are change control processes in healthcare support services and healthcare delivery standards. However, these are in the context of quality management and lack requirements for proactive evaluation and assessment of safety risks associated with proposed changes.
3.3 Proactive Risk Management

3.3.1 Aviation

Safety risk management is a component of aviation safety management system and includes hazard identification, safety risk assessment and mitigation [46], [48], [50], [52]. Aviation organizations understand that hazards exist at all levels of an organization and with the correct precursors, they could lead to serious incidents or accidents [52]. As such, aviation organizations must continually identify hazards and mitigate safety risks [52]. In aviation, hazard identification is based on a combination of proactive, predictive, and reactive safety data collection [46], [48], [50], [52]. These approaches are described in Table 3.

Table 3 - Hazard Identification Approaches in Aviation

<table>
<thead>
<tr>
<th>Approach</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proactive</td>
<td>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 [52]</td>
</tr>
<tr>
<td>Predictive</td>
<td>Gathering data to identify potential negative future outcomes or incidents, analysing systems, processes, and the environment to identify possible future hazards and initiating mitigating actions [52]</td>
</tr>
<tr>
<td>Reactive</td>
<td>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 [52]</td>
</tr>
</tbody>
</table>

Aviation safety hazards may be identified through a variety of techniques such as group brainstorming sessions with operational and technical experts, normal monitoring of operations, voluntary and mandatory incident reporting systems (internal and State), safety surveys, internal safety audits, and state oversight programme, feedback from training, investigation and follow-up reports on accidents or incidents, information exchange systems, and industry accident reports [52].
In addition to the methods above, organizational changes, changes to regulatory requirements and operations may introduce new hazards and need to be assessed for impact on safety in accordance with the aviation Management of Change (MOC) process [46], [48], [50], [52], [64].

A mature SMS considers human factors and human performance during the safety risk management process. Aviation is complex given the number of systems, personnel, organizations, and processes involved. Such complexity may affect human performance and lead to errors and safety risks. In aviation, errors are considered normal and unavoidable. However, they can be reduced and controlled with appropriate system analysis and design. Therefore, hazard identification and analysis should also be applied to (1) design of tasks, technology, and the environment, (2) cognitive, physiological, and psychological limitations to human performance, (3) procedures and operating practices and their validation under actual operating conditions, and (4) organizational factors. [52]

Aviation organizations are recommended to assess operational and organizational systems and components and how humans interact with these to identify potential areas where errors may occur. In this analysis, a model called “SHELL” (Figure 8) may be used to analyze interactions of multiple system components. The shell model has four components: Software, Hardware, Environment, and Liveware. In the centre of the model is liveware which includes humans working in the system. There are 4 interfaces with liveware: liveware-liveware, liveware-software, liveware-hardware, and liveware-environment. It is understood that humans are not standardized and there will be variation in their performance and may face challenges when interfacing with other components of a system. A mismatch between the human and any of the other four components may lead to a human error. [52]

The interface between the different SHELL components is explained in Table 4, on the next page.
Figure 8 - The SHELL Model from ICAO Safety Management Manual [52]

![SHELL Model Diagram]

Table 4 - Description of Interfaces Between the SHELL Model Components

<table>
<thead>
<tr>
<th>Interface Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liveware-software (L-S)</td>
<td>The L-S interface is the relationship between the human and regulations, manuals, checklists, publications, standard operating procedures and computer software. This interface includes experience, presentation and format, accuracy, vocabulary, clarity and symbology. [52]</td>
</tr>
<tr>
<td>Liveware-Hardware (L-H)</td>
<td>This interface is commonly considered in aviation organizations and is the relationship between the human and the equipment, the facility and the machines. [52]</td>
</tr>
<tr>
<td>Liveware-Environment (L-E)</td>
<td>This interface is the relationship between the human and the environment consisting of the internal and external environment. Examples include temperature, ambient light, noise, air quality, physiological and psychological forces (illness, fatigue, financial and personal concerns). Organizational attributes such as pressures to work around problems and to deviate from normal operating procedures may impact this interface. [52]</td>
</tr>
<tr>
<td>Liveware-liveware (L-L)</td>
<td>The L-L interface is the relationship between people in the workplace. At this interface, the importance of communication, interpersonal skills, group dynamics and their impact on human performance should be recognized, especially for organizations that rely on teams and teamwork. Crew resource management, staff/management relationships, and organizational culture fall under this interface. [52]</td>
</tr>
</tbody>
</table>
Following hazard identification, a hazard analysis needs to be completed. This when hazards are assessed for their significance, and mitigated or eliminated using safety risk controls [48], [52], [56], [64].

Safety risk management in aviation includes assessing risks with respect to their probability of occurrence, their severity, and the tolerance of the organization to accept the safety risks. Risks may be categorized under acceptable, tolerable, or intolerable. Intolerable risks are the ones that are unacceptable and must be addressed under any circumstances. Tolerable risks are acceptable yet they still require appropriate safety risk controls in place.

Safety risk controls in aviation may include application of new technologies or modification of existing technologies, processes, operating procedures, and training programs. They also may include one or a combination of avoidance, reduction, and segregation of exposure to ensure an optimal solution. Risk controls that include human elements need to be evaluated to ensure that human factors have been taken into consideration. Other factors taken into consideration when selecting a safety risk control include: (1) effectiveness, (2) cost/benefit, (3) practicality, (4) durability, (5) unintended consequences, and (6) residual risk. [52]

Once safety risks have been analysed, assessed, and mitigated, the risk management loop needs to be closed through a process called “safety assurance”. As part of this process, aviation organizations are required to continually monitor the performance of the SMS, 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, and establish safety performance indicators / targets / objectives to validate the effectiveness of the implemented safety risk controls by verifying the safety performance against these established criteria [46], [48], [50], [52], [56], [64].

Safety assurance complements quality assurance. They differ in that quality assurance monitors compliance with regulatory requirements and safety assurance monitors the effectiveness of safety risk controls. Safety performance of aviation organizations may be measured and monitored using (1) voluntary and mandatory incident reporting systems and investigations, (2) safety studies, (3) safety reviews (a fundamental component of the management of change), (4) safety surveys, and (5) internal and external audits.
Many of the concepts explained above are applicable to predictive and proactive safety risk management. Aviation also performs reactive safety management. Aviation occurrences are divided into 5 categories or classes. The type of investigation, level of effort, investment and investigation process and timelines are dependent on the type of occurrence. Occurrences that are Class 1 and 2 require exhaustive and detailed investigation with expected completion between 600 to 730 days [128]. Occurrences that are Class 3 require less intense investigations that are completed within 450 days [128]. Occurrences that are Class 4 require limited scope investigations that are to be completed in 200 days [128]. Occurrences that are Class 5 do not require a full investigation and only need data collection and should be completed within 60 days [128].

3.3.2 Nuclear Energy

Similar to aviation, nuclear energy organizations are mandated to conduct safety assessment of construction, design, and operation of nuclear power plants. Nuclear energy’s safety analysis and assessment process initiates at the design stage, continues through the construction phase of a nuclear power plant, and is periodically repeated during the operational life-time of a nuclear power plant[70], [76], [85], [93]. Safety assessment and analysis are also completed if modifications are made to the plant or the processes/procedures that would have safety impacts on the facilities and activities [74].

The IAEA defines safety assessment as “the assessment of all aspects of a practice that are relevant to protection and safety. For an authorized facility, this includes siting, design and operation of the facility.”[70]. Nuclear energy organizations are required to conduct a systematic safety analysis and assessment of all facilities and activities, all possible failure modes, and the consequences of such failures [67], [70]. Hazards or accident precursors in a nuclear power plant may also be identified through operating experience feedback and analysis [67], [70]. Operating experience feedback is a process where a nuclear plant learns from safety related concerns, situations that could give rise to errors, procedural deficiencies, near misses, incidents, and accidents (as a result of operating error, equipment failure, unintended actions by the operator, and unauthorized acts) that have occurred at that plant and at other nuclear power plants[77]. Nuclear energy standards state that operating experience from other nuclear facilities shall be taken into consideration even if there are differences in the design and operational procedures
between the plants [77]. Deficiencies in a nuclear power plant may be identified through audits, self-assessments, walkdowns, regulatory inspections, trending, surveillance, and peer reviews [77].

All reported near misses, incidents, and accidents need to be evaluated for their significance and prioritized based on the safety consequences and potential for their recurrence [77]. Assessments also include proposing safety measures or corrective actions and evaluation of the effectiveness of these actions [67]. Immediate corrective actions need to be identified and implemented based on the significance and the potential for recurrence of the near-miss, incident, or accident [77]. Long-term and more permanent corrective actions shall be appropriate and based on the assessment and evaluation of the near-miss, incident, or accident and evaluated for their effectiveness [77]. The process of safety analysis, assessment and control has to be satisfactory to the regulatory body for a nuclear power plant to begin construction and operations [67].

As described in the previous chapters, nuclear energy recognizes human limitations such that the IAEA and CNSC require human factors to be taken into account for the design and operation of nuclear facilities and the planning and conduct of nuclear activities [70], [71]. Safety assessments also need to take into account human performance and human factors and be performed on safety measures that involve operator intervention to demonstrate that interventions are robust and reliable prior to implementation [67]. The human factors safety assessment includes factors related to ergonomic design, human–machine interfaces, fitness for duty, fatigue, and workload to allow for optimal operator performance [70], [71]. Safety measures include design of systems that allow easy interaction between the operators and the operating environment, design of processes and procedures such that they are clear and achievable, unambiguous presentation of information [70], and availability of organizational resources such as staff training, support, and adequate human resources during safety critical operations [76].

The process of nuclear energy safety assessment is repeated throughout the life of a nuclear facility and is also referred to as “periodic safety review” or PSR [67], [72], [76]. The purpose of repeating safety assessments is to identify changes (new standards or new technology development), utilize the feedback of the operating experience, and take into consideration the effects of an ageing facility [67], [70].
As part of the nuclear energy management system standards, non-conformances or issues in a nuclear power plant need to be immediately controlled, recorded, and assessed for significance and root-cause [89]. 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 [89].

3.3.3 Healthcare

Healthcare support services have requirements in place for identification, investigation, and evaluation of errors, accidents, and deviations from normal operating procedures and implementation of corrective and preventive actions in response to identified and potential nonconformities [95]–[97], [104], [106], [122].

In healthcare delivery there are requirements for identification, investigation, documentation, evaluation, and correction of deviations from policies and procedures, which have led or could lead to adverse events [98], [117]. Actions must be taken to identify the root-cause(s) of nonconformities, correct and control the nonconformities, and in instances where possible eliminate the root-cause of nonconformities [117].

As previously stated, there are specific standard requirements for safety assurance in healthcare support services and healthcare delivery. However, within the healthcare support services and healthcare delivery quality management system requirements, there are requirements for quality assurance and establishments must monitor the results of implemented corrective and preventive actions to verify their effectiveness in overcoming quality problems [95], [97], [106], [107], [117]. Ontario has acts and regulations related to quality improvement and mandatory reporting, disclosure (to the affected patients, their caregivers or families), and investigation of critical incidents. The Hospital Management regulation [112], under the Public Hospital Act [110], states that a system needs to be established for a hospital appointed committee to review and analyze every critical incident that has occurred and develop a mitigation plan to reduce or eliminate the risk of future similar critical incidents. The hospital is also required to establish a quality committee and have the critical incidents data shared with this committee [112]. The quality committee is required to be established and maintained under the Excellent Care for All Act (EFCAA) [111]. The quality committee’s objectives are to monitor and report quality of the services provided by the healthcare organization as well as any quality issues, ensure information on the latest best practices and resources related to these practices are communicated and made
available to the employees, and recommend and prepare quality improvement initiatives and plans [111]. The quality improvement plan shall include the following indicators: (1) safety; (2) effectiveness; (3) patient-centredness; (4) efficiency; (5) timeliness; (6) equity; and (7) workplace violence prevention [113].

Healthcare support services and healthcare delivery standards make references to investigation and evaluation of deviations from normal operations. However, these are in the context of quality deviations and are not safety focused. Healthcare delivery standards [98], [117] lack requirements and guidelines for safety hazard identification, proactive safety risk assessment, and safety risk control effectiveness verification. Furthermore, unlike aviation and nuclear energy standards and guidelines where emphasis is placed on human performance, human factors, and actions that need to be taken to ensure that sources of human error are eliminated or controlled, healthcare delivery standards lack these requirements.

The CPSI Canadian Incident Analysis Framework [109] is a document that describes in detail actions and processes that can be taken to manage incidents. Included in these actions or processes are (1) incident reporting; (2) incident analysis through interviews; (3) use human factors and systems theory and diagramming to identify the root-cause (4) recommend corrective actions to eliminate the risks or reduce the risk of recurrence (5) follow through to assess the effectiveness of implemented corrective actions; and (6) share the lessons learned.

This framework specifies that effective corrective actions are written in the **SMART** format:

**Specific** - Tackle a clearly defined issue and have a clear scope

**Measurable** - can demonstrate impact on process and outcomes

**Attainable** - can be achieved with available resources

**Realistic** - do a reality check to predict if it will be accepted

**Timely** - have a timeframe for implementation

Human factors hierarchy of effectiveness is also recommended to be used as a tool and a guide for development of effective corrective actions. The Canadian Incident Analysis Framework is the only document reviewed that referred to the importance of human factors and the need to
conduct cognitive walkthroughs, usability tests, and heuristic evaluations following incidents as techniques to understand the context of an accident/incident.

3.4 Fatigue Management

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.” [46].

Worker fatigue is considered a safety hazard in safety-critical industries that operate on a 24-hour basis. It is understood, in safety-critical industries such as nuclear energy, that fatigue declines human performance, alertness, and cognition [84]. 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) [54].

3.4.1 Aviation

Negative impacts of fatigue on aviation flight crew’s performance are well-studied and are the primary reason why the aviation industry enforces limitations on flight time, flight duty period, duty period, and rest period [46], [56], [64]. Regulators have “fit for duty” requirements and expect the flight crew to be well rested and ready to perform their duties before the start of their flight duty period [64].

Transport Canada, the Canadian aviation regulator, requires that aviation organizations have an FRMS in place to monitor the flight times, flight duty periods, work hours, and rest periods for all flight crew members [56]. In aviation, an 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.”[46].

An FRMS, required by Transport Canada, includes similar components as an SMS. FRMS components are summarized below [46], [56], [64]:

1. A fatigue risk management plan (policy, objective, safety performance indicators, responsibilities)
2. A fatigue risk management process (internal reporting of fatigue, identification of fatigue related hazards, fatigue risk assessment, fatigue risk mitigations and control, developing safety indicators to evaluate the effectiveness of the mitigations and controls)

3. A quality assurance program for the fatigue risk management system (continuous monitoring and auditing of the FRMS to evaluate its effectiveness); and

4. A program for fatigue risk management promotion (employee training on processes and components of the FRMS)

Transport Canada requires that any changes to work schedules be assessed for their impact on flight crew fatigue and consider the consequences and impact on safety [56]. There are standards, guidelines, and fatigue risk management toolkits that are in place to enable aviation organizations to effectively manage fatigue and implement an FRMS [46], [53]–[55], [58]–[61]. Transport Canada also has an FRMS toolbox [61] which includes guidelines that are 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 [58], [59].

The International Air Transport Association (IATA) in collaboration with the International Federation of Airline Pilots’ Association (IFALPA) and ICAO have published a guidance [54] for fatigue management of airline operators based on the ICAO’s Annex 6 [46], [47], [53]. In this guidance document, the basic science behind sleep, factors affecting sleep quality, impact of reduced or low quality sleep, operational and organization components of an FRMS, examples of fatigue hazards, and a description of fatigue risk management processes including hazard identification, risk assessment and mitigations are detailed [54].

3.4.2 Nuclear Energy

The IAEA requires nuclear power plants to have processes in place to identify and control aspects of operations that influence human performance and fitness of employees, including fatigue [72]. Managers are encouraged to use administrative controls to identify and control the fitness for duty of shift workers. Examples of such controls are monitoring and paying particular attention to signs of physiological and mental health of workers and limiting work hours to minimize fatigue [75].
In line with IAEA requirements, the Canadian nuclear regulator, Canadian Nuclear Safety Commission (CNSC) has published a regulatory document titled *REGDOC-2.4.4, Fitness for Duty: Managing Worker Fatigue*[84] 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[84]. Night work, overtime, and the number of consecutive shifts are also important aspects of work schedules that should be considered in managing fatigue [84].

It is understood that there are factors outside of work, in a person’s personal life that may affect fatigue and therefore management and workers share the responsibility of reporting and managing fatigue. One guidance that is provided on managing worker fatigue is to schedule safety-critical tasks outside of fatigue peak hours (especially between 2 am and 6 am).[84]

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. [84]

Similar to Canada, the United States also has regulations [99] 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 [99]:

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

Follow-up to (1) where there was cause to believe that a worker was fatigued.
3.4.3 Healthcare

Research on the effects of fatigue on healthcare provider’s performance suggests that longer work hours are associated with declining performance, increased likelihood of mistakes, and occurrence of near misses [129]–[132]. A pilot study on the relationship between work and sleep on Australian nurses showed that nurses slept fewer hours on workdays compared to non-work days. 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 [129].

Increased shift length and 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 [130].

Increased fatigue levels can also negatively impact tasks that are longer in duration and need attention to detail (patient monitoring, documentation and medication administration)[133]. 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 [131]. 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 lack of empathy[134]–[136].

Healthcare workers’ fatigue is linked with increased risk of adverse events and compromised patient safety [134], [135]. 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[134], [135]. This standard established requirements on the maximum number of hours a physician in training can work (80 hours/week) and use of fatigue management strategies [134], [135], [137].

There are studies that suggest that restricting shift hours, in most cases, has no impact on patient care or resident well-being, and has a negative impact on resident learning[138]. Based on these findings, ACGME decided to remove the 16-hour limit for first-year residents in 2017 [138], [139]. The United States is not the only country that has recommended a limit on resident duty hours. 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 many other NHS staff[138], [140]. 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 [136]. 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 [136].

The Resident Doctors of Canada 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 [141]. 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 9) [141]. If the countries mentioned above were to be evaluated using this criteria, Canada and the United States would rank as a higher fatigue risk while Europe and Australia would rank as a lower fatigue risk.

**Figure 9 - Fatigue Risk Levels: 7 Day Period from Resident Doctors of Canada: Fatigue Risk Management Toolkit [141]**

<table>
<thead>
<tr>
<th>LOWER RISK</th>
<th>SIGNIFICANT RISK</th>
<th>HIGHER RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 50 hours worked</td>
<td>50 to 70 hours worked</td>
<td>More than 70 hours worked</td>
</tr>
<tr>
<td>No more than 10 consecutive hours in any one period</td>
<td>Up to 14 consecutive hours in any one period</td>
<td>14 or more consecutive hours worked at least twice</td>
</tr>
<tr>
<td>Three or more short breaks taken during daily working hours</td>
<td>One or two short breaks during daily working hours</td>
<td>No short breaks during daily working hours</td>
</tr>
<tr>
<td>Little or no unscheduled extra work</td>
<td>More than 10 hours extra unscheduled work</td>
<td>More than 20 hours unscheduled extra work</td>
</tr>
<tr>
<td>Scheduled on call for less than 3 days in seven days</td>
<td>Scheduled on call for 3 days or more in a 7 day period</td>
<td>Scheduled on call continuously for more than 7 day period</td>
</tr>
<tr>
<td>No night work</td>
<td>At least 2 nights of work or extended hours into the night</td>
<td>At least 3 nights of work or extended hours into the night</td>
</tr>
<tr>
<td>Minimum 10 hour breaks between work periods and 2 days free of work</td>
<td>Minimum 10 hour breaks between work periods and one day free of work</td>
<td>Less than minimum 10 hour break on at least two work periods and no full day free of work</td>
</tr>
</tbody>
</table>
Queensland Health in Australia published an 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 aviation FRMS implementation guide [134], [142].
3.5 Reliability of Safety Critical Tasks

3.5.1 Aviation

Aviation regulations and standards on reliability mostly address the technological reliability. Aviation organizations must demonstrate reliability of an aircraft and aircraft components to obtain a certificate of airworthiness [51], [56]. A certificate that declares an aircraft airworthy, confirms that the aircraft, engine, propeller or part meets to its approved design and is in a condition for safe operation [51]. Reliability in aviation technology is achieved through independence of engines from other engines, from main electrical supply and associated systems [46], [51]. In the event that an engine fails, it will not compromise the safety of the aircraft because the systems have been separated [46], [51]. Other means of achieving reliability in aviation is through the use of technology, emergency systems, and redundant components [46], [51].

Many of aviation operations are performed by humans. Humans are known to be susceptible to making errors [52]. Errors can be managed and reliability of processes performed by humans can be increased by either eliminating factors that contribute to errors (reduction strategy), capturing the error before adverse consequences (capturing strategy), and increasing the tolerance of systems to errors (tolerance strategies) [52]. Reduction strategies include improving ergonomic and environmental factors (reducing distractions). Capturing strategies include the use of checklists and procedure [52]. Tolerance strategies include designing systems with the ability to absorb errors using redundant systems and multiple inspection processes [52].

3.5.2 Nuclear Energy

Reliability is an important characteristic and requirement of systems important to safety (SIS) in a nuclear power plant [88]. Any nuclear power plant must provide documentation and description of a reliability program as a requirement to obtain an operating license [88]. The objective of a reliability program is to provide assurance that all systems important to safety function per the design specifications and perform reliably as intended [88]. Nuclear energy standards state that reliability in nuclear power plants can be achieved through concepts of redundancy, physical separation, functional independence, and single failure criterion [71], [92].
Redundancy in nuclear power plant design can be achieved through the installation of redundant systems or safety components [71], [92]. Redundancy can provide assurance that in the event that a safety system malfunctions, the back-up safety system can be relied upon to maintain safe operation of a nuclear power plant [71], [92].

Different safety systems, safety systems and process systems and redundant components of safety systems need to be separated and independent of one another [71], [92]. Separation and independence can provide assurance that any failure in a system will not result in the failure of a safety system or other systems [71], [92].

Nuclear energy organizations shall conduct periodic safety review and analysis on their systems and components to ensure that no single failure of a component affects the operation of other components and safety systems so that reliability and safety is maintained [92].

The concepts mentioned above, also form the basis of defence in depth. Defense in depth can be applied to all safety related activities and ensures that behavioral, 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) [67], [71].

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 [67], [71]. Defence in depth is shown in Figure 10 and the purpose of each level in the context of nuclear safety is described in greater detail in the next paragraph.
The purpose of the **first level** of defence is to prevent failure of safety critical components and deviations from normal operation [71]. To successfully implement and maintain this level:

- the nuclear power plant has to be designed, constructed, maintained and operated in accordance with quality management and proven engineering practices [71].
- attention must be paid to selection of design codes and material and quality control for components [71].
- probability of safety risks must be reduced and accident occurrences must be prevented using design options that reduce potential for hazards [71].
- attention must be paid to the processes and procedures involved in design, manufacture, inspection, maintenance and testing, and to plant operations [71].
- detailed analysis must be completed to determine quality management and maintenance requirements [71].

It is understood that over the lifespan of a nuclear power plant, systems and safety components may fail and therefore a **second level** of defence is required [71]. The **second level** is to detect and control deviations from normal operation and to prevent them from escalating to accident conditions [71]. To implement and maintain this level:
• specific features and systems need to be provided in the plant design [71].
• specific features and systems effectiveness need to be validated and verified through safety analysis [71].
• operating procedures need to be developed to prevent occurrences from escalating to accident conditions [71].

The third level of defence is to prevent damage to the reactor, release of radioactive material and bring the plan back to a safe state. This level requires safety features, safety systems, and procedures [71].

The fourth level of defence is to prevent progression of accidents that result from failure of the previous level and mitigate the consequences of such accidents. This is accomplished by having protective measures to ensure radiological release does not extend to outside of the nuclear power plant site [71].

The fifth and final level of defence is to mitigate the radiological consequences of radioactive releases that could potentially result from accidents. This requires adequately equipped emergency response plans, facilities, and procedures [71].

Similar to aviation, nuclear energy operations are also dependent on humans. Reliability in nuclear energy is not limited to technology and is dependent on humans. Nuclear power plants are required to conduct probabilistic safety assessments (PSAs) [76]. PSA is a comprehensive method of identifying all failure modes and scenarios of a nuclear power plant [70] and includes human reliability analysis [76]. In human reliability analysis, actions of the operator specific to a plant and specific to certain tasks are modelled. Similar to aviation where human errors are reduced and managed, nuclear energy also requires human errors to be reduced and the integrity of controls or weak safeguards to be improved.

Human error reduction strategies in nuclear energy are briefly explained below:

1. **Preparation:** Includes identifying the scope of the work, associated hazards, actions to avoid, critical steps, potential challenges to error-free performance and selecting the right individuals for the task.
2. **Performance:** Includes maintaining work with a sense of comfort/ease, maintaining situational awareness, and avoiding unsafe work practices.
3. **Feedback:** Includes reporting, behaviour observations to communicate and convey information on quality of the work performed, work-place conditions and to coach workers on their performance in the field.

Despite implementing reduction strategies, errors do still occur. It is therefore necessary to have effective control strategies in place to contain errors once they have occurred. Control strategies may include elimination or substitution, engineered features, administrative controls, cultural norms and oversight. Each control strategy has benefits and limitations. It is expected that control strategies that are performed by humans and depend on them are less effective and reliable than those that are automated and technology dependant. Controls need to be managed, verified and validated to ensure they are effective.

Nuclear energy defines several symptoms indicative of a declining safety culture and reduced reliability. Some notable ones are listed below [78]:

- 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 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. short cuts.
- An increasing backlog of corrective actions — Corrective actions exceeded 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.
3.5.3 Healthcare

There were no regulations, standards, or guidelines identified in healthcare support services and healthcare delivery related to reliability of processes and operations.
3.6 Summary

Aviation has specific regulatory requirements for implementation of safety management systems. Similarly, nuclear energy is also mandated to implement an integrated management system (including safety). Aviation and nuclear energy management systems are required to include process control, a management of change process, proactive and predictive hazard identification and risk management, fatigue management, and reliability analysis. Both industries take into consideration and emphasize the importance of design and human factors to facilitate error free operations.

In contrast, no specific regulations for healthcare delivery services have been identified. Healthcare regulations that have been identified are specific to healthcare support services such as blood products, transplantation, and medical device manufacturing. Healthcare delivery lacks regulations and standards on application of safety management systems, control processes such as validation and verification and the management of change process, proactive hazard identification and risk management, fatigue management, and reliability.
4 Gaps in Practice: Aviation, Nuclear Energy, and Healthcare

4.1 Methodology

4.1.1 Stakeholder Identification

As summarized in Chapter 3 (Sub-Chapter 3.6), review of aviation, nuclear energy, and healthcare regulations and standards identified that healthcare lacks regulations and standards on safety management systems, control processes such as validation and verification and the management of change process, proactive hazard identification and risk management, fatigue management, and reliability.

To understand which regulations, standards, and practices are implemented in aviation, nuclear energy, and healthcare, SMEs from all three industries were identified and invited to participate in semi-structured interviews. 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. Healthcare stakeholders were identified based on their knowledge and understanding of patient safety initiatives and challenges and their experience with safety and quality standards. The backgrounds and associations of these SMEs are presented in Figure 11.

**Figure 11 - SMEs Interviewed from Aviation, Nuclear Energy, and Healthcare**
4.1.2 Semi-Structured Interviews

Semi-structured interviews were conducted with the ten SMEs, listed in Figure 11, from September 2018 to November 2018.

Five interviews were conducted over the phone and five were conducted in person. The duration of the interviews ranged from 30 to 60 minutes.

For the purpose of these interviews, two questionnaires were prepared. The questions for aviation and nuclear energy industry were framed around application of process control, change control, proactive hazard identification and risk management, fatigue management, and reliability. The purpose of the line of questioning was to verify the elements that are in the standards and regulations and the extent to which these are applied in the actual practice and to identify challenges that were experienced with implementation of these practices.

The healthcare questionnaire 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, we aimed to identify the benefits and challenges of implementation of the previously identified quality and safety processes.

The interview questionnaire that was used to facilitate the semi-structured interviews with aviation, nuclear energy, and healthcare SMEs is presented in Appendix E.

4.1.3 Qualitative Analysis

All semi-structured interviews were audio recorded and the recordings were transcribed for analysis. Thematic analysis was used as the technique to identify themes and develop recommendations for further action. A six-phase approach proposed by Braun and Clarke [143] was taken to conduct the thematic analysis. The six phases are (1) familiarizing yourself with the data; (2) generating initial codes; (3) searching for themes; (4) reviewing potential themes; (5) defining and naming themes; and (6) producing the report [143].
Familiarization with the data was achieved by transcribing the audio recordings, reading the transcriptions, re-listening to the audio recordings, taking additional notes, and reviewing the notes taken during the interviews.

A deductive thematic analysis approach where themes are theory-driven, was undertaken to allow addressing the specific research question of “what safety and quality processes are implemented in aviation, nuclear energy, and healthcare delivery?” Therefore, the initial codes were descriptive and described the content of the data or summarized a portion of the data. The first reviewer (Andia Toomari) interpreted the transcriptions and notes and created the initial codes. The first reviewer then reviewed the coded data and searched for themes with the codes. The second reviewer (Dr. Joseph Cafazzo) reviewed the potential themes and with the first reviewer, they named and refined some of the themes to better reflect the data. The following themes were derived from this thematic analysis:

- Lack of explicit safety management system in healthcare delivery
- Lack of control processes to ensure uniform, consistent practice in healthcare delivery
- Lack of proactive risk assessment 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

The identified themes are discussed in greater detail in the following section (Section 4.2).

4.2  Discussion

4.2.1  Safety Management Systems

From interviews with aviation and nuclear energy subject matter experts, 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 responsibility for implementation on individual aviation organizations. Under the safety management system there are explicit requirements that aviation organizations need to satisfy for them to be able to be granted or maintain their license for operations.
Similarly, nuclear energy SMEs identified the *N286 CSA standard - general management systems* 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 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.

In contrast to aviation and nuclear energy industries, no such rigour or systemic management system approach to safety or quality is taken in healthcare delivery. Care is often delivered with a high degree of personal, professional autonomy, interpreted as an independent practice and is self-regulated, in contrast to other safety-critical industries.

### 4.2.2 Process Control and Management of Change

Aviation and Nuclear Energy SMEs specified that these industries have change control and process control processes in place to ensure safe and standardized practices.

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

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 authorised personnel including engineering, operations, and maintenance to ensure that design and safety requirements are met.
Stakeholders from both industries have 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.

Healthcare stakeholders stated that such standards on process and change control do not exist in healthcare delivery. Radiation medicine within certain hospitals have implemented process and change control and have the introduction of new technologies, processes, or changes reviewed by a designated committee. However, this practice is an exception and not generally used in healthcare delivery.

4.2.3 Proactive Hazard Identification and Closed Loop Risk Management

Aviation and Nuclear Energy SMEs stated that these industries 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 found to be in contrast to healthcare where mitigations are commonly implemented with their effectiveness in reducing patient safety risk is left unmeasured, thus constituting an open risk management loop.

Aviation and nuclear industry's risk assessment process and mitigation planning is driven by safety requirements and is not 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 built the same way or use the same equipment/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 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 anticipating new hazards.

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:

- Summarizing 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 change control process as changes have the potential to introduce new hazards to the system.

Similar to the change control process 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 practiced 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. Proper assessment of an identified hazard or an 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 organization 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. In healthcare service delivery, 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.

Unlike aviation and nuclear energy, adverse events and near misses in healthcare are not investigated or resolved properly due to inadequate risk assessment procedures and mitigations. 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 safety verification 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 safety management loop in healthcare delivery is open. This may be as a result of lack of follow up on implemented mitigations to ensure that they are successful in reducing patient safety hazards. In healthcare delivery such data is not routinely collected or analyzed which may result in adverse events recurring.

4.2.4 Fatigue Management

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

Similarly, nuclear energy SMEs stated that 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.

Healthcare SMEs stated that worker fatigue is an area of concern in healthcare delivery, specifically in trainees. There have been rules created around the number of hours that trainees can work, however these rules serve as only guidelines. Having interviewed a number of physicians, they were unclear of the specifics of the guidance for staff. Stakeholders have identified that the 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.

4.2.5 Reliability of Safety-Critical Tasks

Aviation and nuclear energy ensure the reliability of their processes and technologies. Nuclear energy has comprehensive and detailed reliability standards and requirements whereas in
healthcare delivery reliability is uncommon, not taken into account during risk mitigation development, and not designed into healthcare delivery processes.

Aviation must ensure reliability of their processes as part of their 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.

Nuclear energy is obligated to ensure reliable operations as their standards speak to having redundancy, separation, and independence of systems. Nuclear Energy SMEs stated that there are two types of reliability in nuclear industry; equipment reliability and human reliability. Both equipment and human reliability can be achieved by applying the concept of defence in depth.
5 Validation of Themes

5.1 Member Checking

Member checking or participant/respondent validation is a technique in qualitative research to validate the accuracy and credibility of the results. In member checking, the results are given back to participants to determine if the results resonate with the participant’s experience. [144]

The member checking exercise for this project was conducted in the form of a focus group with healthcare stakeholders from various disciplines and functions from Ontario based organizations including the University Health Network (UHN), St. Michael Hospital, The Hospital for Sick Children, Sinai Health System, and UHN Healthcare Human Factors. More details of the roles of participants are presented in Table 5.

A total of 12 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. The duration of the focus group was approximately two hours and it included introduction of the project, methods used, and results of the thematic analysis. Round table discussions were held following presentation of each theme and providing more information such as examples of practices in aviation and nuclear energy.

### Table 5 - List of Discipline and Roles of Member Checking Participants

<table>
<thead>
<tr>
<th>Role and Title</th>
<th>Discipline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director of Quality &amp; Innovation of the UHN Emergency Department</td>
<td></td>
</tr>
<tr>
<td>Director, Professional Practice &amp; Policy</td>
<td></td>
</tr>
<tr>
<td>Medical Director of IT Implementation and Innovation</td>
<td></td>
</tr>
<tr>
<td>Section Head, Cardiomyopathy &amp; Heart Function Program Cardiology</td>
<td></td>
</tr>
<tr>
<td>Lead, Human Factors &amp; Patient Safety</td>
<td></td>
</tr>
<tr>
<td>Senior Professional Practice Leader</td>
<td></td>
</tr>
<tr>
<td>Director, Professional Practice</td>
<td></td>
</tr>
<tr>
<td>Vice President, Quality and Safety</td>
<td></td>
</tr>
</tbody>
</table>
5.2 Findings and Discussion

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 incentivizing training, and lack of reliability, resilience and systems thinking.

One issue that participants stated is 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 that was mentioned was the lack of communication of who the decision makers are and what the decision-making mechanisms are in healthcare organizations.

There were discussions on the lack of safety communication within all areas of an organization and although safety huddles take place now, they 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 several 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 in healthcare.
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 following 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.

The issue of variability in healthcare delivery processes was raised often. Variability was mentioned as the reason 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 brought up again.

Root-cause identification and analysis in healthcare delivery relies on too many meetings and may take weeks to months to complete. Another challenge with respect to risk management that was mentioned by participants 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 from nurse practitioners where they are expected to also perform longer hours.

The approach that healthcare takes to fatigue management is one that interprets fatigue as a character flaw rather than a system issue. 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 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 which place staff in moral distress due to the expectations to continue with a specific task.
6 Potential Application of Safety Management System Processes in Healthcare Delivery

As stated in Chapter 4, one of the objectives of the interviews with healthcare stakeholders was to identify healthcare delivery areas where application of safety management system principles would be beneficial. Through the interviews with healthcare stakeholders, it was identified that the radiation oncology units in a few hospitals have implemented safety management system processes such as process control and the management of change. Stakeholders recommended chemotherapy as another unit that could benefit from the application of safety management principles since there are many parallels in medical oncology.

Preliminary observations were completed at the systemic therapy unit in Princess Margaret Cancer Centre on Friday August 2, 2019 in the systemic therapy unit and on Wednesday August 7, 2019 in the pharmacy.

An overview of the systemic therapy unit and the pharmacy and an initial attempt of the application of the findings with respect to safety management system processes are provided below.

6.1 Systemic Therapy Unit Overview

Patients are scheduled for their systemic therapy appointments months in advance. The scheduling is done through scheduling software that allows the prescribing physician to select and assign a treatment protocol to each patient.

Patients are required to have a blood work done days ahead of their treatment or on the day of the treatment. The purpose of this is to (1) modify the treatment protocol depending on the results of the blood test or (2) determine if the patient can proceed to the next treatment. If the prescribing physician determines that the patient needs to receive a modified treatment or one that is different from the initial prescribed treatment protocol, he/she needs to update the treatment protocol in the scheduling software. The physician also needs to input the treatment protocol in the systemic therapy Computerized Physician Order Entry (CPOE) otherwise known as Oncology Patient Information System (OPIS). OPIS and the scheduling software do not
communicate with each other and therefore need to be updated separately. A simple process flow diagram for the process described above is presented in Figure 12 and Figure 13.

Figure 12 - Process Flow Diagram of Systemic Therapy Scheduling and Prescribing (Scheduling System)

![Process Flow Diagram of Systemic Therapy Scheduling and Prescribing](image1)

Figure 13 - Process Flow Diagram of Systemic Therapy Prescribing (OPIS)

![Process Flow Diagram of Systemic Therapy Prescribing](image2)

On the day of the treatment, patient arrives at the clinic and checks in. The administrator updates the “whiteboard” to indicate that the patient has arrived. The whiteboard is a system that pulls data from the scheduling software and OPIS. The whiteboard displays the names of all patients scheduled for treatment along with their appointment times. The whiteboard also allows tracking of information on the status of (1) patient’s blood tests (2) pharmacy’s medication preparation progress and (3) which of the four treatment pods the patient is assigned to. These are described in more detail in the following paragraphs.

A systemic therapy unit administrator continuously monitors the whiteboard for patients who have arrived. Once the whiteboard indicates that the patient has arrived, the administrator checks to see (1) the status of blood work for the patient (indicated on the whiteboard) and if the results are all within an indicated range, the administrator assigns the patient to one of the four treatment pods, if there is a spot available, and enters which pod he/she has been assigned to on the whiteboard.

The pharmacy receives the medication order and verifies that the treatment protocol entered in the scheduling system matches the one entered in OPIS. If pharmacy observes that the treatment
protocols do not match, they are required to verify the correct protocol by consulting with the prescribing physician before they begin medication preparation.

The pharmacist then places the prepared medication in a bin with the patient’s name written on it. The bin with the medication is placed inside a secure pick up room inside the pharmacy, and the pharmacist updates the whiteboard to indicate that the medication is ready for pickup.

Once it is indicated on the whiteboard that the medication is ready for pickup, a nurse picks up the medication from the medication pickup room inside the pharmacy and verifies that the treatment protocol entered in scheduling system matches that entered in OPIS. If there are discrepancies between the two, the nurse has to double check with the prescribing physician to identify the correct treatment protocol. Once all necessary verifications are completed, the nurse administers the treatment protocol to the patient.
6.2 Initial Recommendations

Based on initial observations, changes can be made to the existing scheduling system, OPIS, and whiteboard in the systemic therapy unit to increase reliability and to identify hazards and areas where human interaction with the systems may lead to errors.

Application of Defence in Depth and Reliability Analysis

Human and technological reliability can be applied in systemic therapy to the scheduling system, OPIS, and the whiteboard. Currently, the prescribing physician needs to update both the CPOE and the scheduling system with the modified treatment protocol. Pharmacy and the systemic therapy unit have access to both systems and can see the treatment protocols specified in both systems. However, if the prescribing physician forgets to update the treatment protocol in the scheduling system, then an error in medication preparation and administration may occur. Currently, the pharmacy and the systemic therapy unit nurse double check or verify the treatment protocol in the scheduling system against that specified in the CPOE. If there are any discrepancies between the two systems, the pharmacist and the nurse have to call the doctor to verify the correct protocol. There are several factors that increase the probability of human error in this process. First, the process is relying on the prescribing physician, a human, to remember and update the scheduling system. Second, the double check and verification is entirely dependent on humans who may miss the discrepancies between the two systems among the many tasks they are responsible for in a busy pharmacy and systemic therapy unit.

The current defence in depth model for the systemic therapy unit is described below and presented in Figure 14:

1. The first line of defence is the prescribing physician. The prescribing physician is required to remember to update the scheduling system if he/she determines that a patient’s treatment protocol needs to be updated.

2. The second line of defence is the pharmacist. The pharmacist is required to verify the treatment protocols specified in the scheduling system and the CPOE and rectify any discrepancies through verification with the prescribing physician.
3. The third line of defence is the nurse. The nurse is also required to verify the treatment protocols specified in the scheduling system and the CPOE and rectify any discrepancies through verification with the pharmacist or the prescribing physician.

**Figure 14 - Current Defence in Depth Model Applied to Systemic Therapy Unit**

Application of reliability analysis in the systemic therapy unit may generate a defence in depth model that is described below and presented in Figure 15:

1. The scheduling system and the CPOE: The scheduling system can be modified to have it automatically updated every time the prescribing physician updates the CPOE with a modified treatment protocol (the prescribing physician would be required to confirm that he/she is changing the treatment protocol). Changes to the treatment protocol are then automatically captured and reflected on the scheduling system and therefore eliminating the need for the prescribing physician to remember to enter the treatment protocol in two separate systems.

2. The Whiteboard: The whiteboard can be modified to have the ability to detect discrepancies between the scheduling system and the CPOE.

3. The pharmacist: The pharmacist can verify that the treatment protocol specified in the CPOE matches that specified in the scheduling system.
4. The nurse: The nurse can also verify that the treatment protocol specified in the CPOE matches that specified in the scheduling system.

5. The pump and Barcode Scanner: At the point of administration and using barcode scanning, possible errors that escaped the previous 4 safety levels can be caught and contained.

**Figure 15 - Improved Defence in Depth Model Applied to Systemic Therapy Unit**

Other improvements that can be made to the existing systems that can potentially increase reliability are

1. Eliminating the scheduling system entirely and integrating its functionality in OPIS. This means that OPIS is the only system where the prescribing physician enters the treatment protocols.

2. The whiteboard can be modified to have it pull the most recent treatment protocol from OPIS.

**Proactive Hazard Identification and Risk Assessment**

Based on initial observations, the usability including the layout of the whiteboard can be improved. However, this requires further analysis and assessment. Proactive risk assessment can be applied to better understand the systems, their interaction and interaction of their individual
components and identify areas where systems can be modified or new systems can be implemented to eliminate or reduce the probability of human error. Examples are:

1. Complete process mapping and human factors analysis in the systemic therapy unit and the pharmacy will allow identification of processes, practices, and systems that may lead to human error.
   a. Human factors observations in the systemic therapy unit with respect to functionality and usability of the whiteboard both for pharmacy and the systemic therapy unit.
   b. The aviation SHELL model can be applied to identify and analyze interfaces between humans, technology, software, procedures, and the working environment and conditions and where potential errors may occur.

**Safety Management System**

A safety management system or specific components of a safety management system can be applied in the systemic therapy unit and the pharmacy that services this unit. Recommendations on specific processes are presented below.

**Management of Change**

Conversations with staff indicated that although there is not a formal and documented management of change process in place, systemic changes are communicated with departments that would be affected. For example, pharmacy would communicate any drug related changes to the systemic therapy to allow for planning and training (if applicable). Implementation of a formal management of change process that entails a comprehensive hazard identification, human factors assessment, and risk mitigation would ensure safer systems, reduced mental fatigue and workload, and increased technological and human reliability leading to increased system reliability.

It is realized that changes like the one described above (treatment protocol changes) are time sensitive therefore the best possible solution for capturing of similar changes is the use of
technology and smart systems rather than a formal change control process which takes time and resources.

Changes that involve addition of new technologies such as procurement or replacement of medical devices, installation of new information systems with direct impact on patient care (such as the scheduling system, CPOE, and the whiteboard) or changes to treatment processes planned for implementation in the future need to be captured using a controlled, documented and formal management of change or change control process.

For management of change to be effective the following are recommended:

1. Approved list of vendors
   a. Procurements from vendors outside of the approved list shall go through a formal management of change process

2. Approved list of medical devices, components, and accessories (i.e Infusion Pumps with approved tubing models and lengths)
   a. Procurement of any device models or accessories outside of the approved list shall go through a formal management of change process

**Pre-Approval & Pre-Assessment**

3. Changes need to be defined and planned for
   a. Affected departments and subject matter experts need to be identified and involved in the hazard identification and risk assessment process (i.e medical engineering, information technology, human factors, clinical units, and patient safety)

**Approval & Assessment**

4. Hazards shall be identified, risks need to be assessed and addressed using reduction or elimination strategies.
a. Functionality assessment shall be performed by medical engineering, information services, and the clinical units

b. Technological assessments and device integration need to be completed by medical engineering

c. Technological and information flow assessments shall be conducted by information services

d. Human factors assessment and analysis need to be completed on the medical devices, information systems, and process flows shall be completed by human factors engineering.

e. Training needs need to be identified for all staff

5. The management of change process needs to be formally documented with approval from all involved groups (i.e medical engineering, Information systems, patient safety, and clinical units)

Post-Approval & Post Assessment

6. Final usability tests or verification runs need to be completed to confirm that identified hazards have been reduced or eliminated and to confirm the effectiveness of the mitigation strategies

7. Management of Change request shall be reviewed for post- approval based on the results of the final usability tests after implementation of mitigation strategies and to confirm that all staff have been trained on the new system additions or modifications

8. Changes need to be communicated to the impacted units by unit leaders
7 Conclusions

Much of the research completed to date with respect to safety learning from safety-critical industries such as aviation and nuclear energy is aimed at tools and techniques that are implemented at the individual or team level as opposed to organizational and system level. Although, healthcare delivery has improved its focus and practice related to risk assessments, root-cause analysis, and human factors engineering and assessments, healthcare continues to see higher rates of preventable adverse events compared to aviation and nuclear energy.

Aviation and nuclear energy are regulated industries where there are international organizations that set rules and standards to harmonize practices and design among all operators. Individual countries have legislations and regulatory bodies to oversee operations, conduct audits, and ensure safety. There are also organizations in aviation that independently carry out investigations into aviation accidents. In contrast to aviation and nuclear energy, healthcare delivery does not have an international organization that sets out rules and standards to harmonize healthcare delivery practices globally. In Canada alone, there are numerous patient safety organizations with no regulatory authority.

Quality management systems defined and used for healthcare settings do not actively identify, assess, and mitigate safety risks. Additionally, it was evident from the literature that there is a lack of requirements for implementation of a safety management system both within standards, regulations, guidelines and in practice in healthcare delivery.

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, hazard identification, and fatigue risk management are not widely practiced in healthcare delivery.

To validate literature review findings and to confirm safety practices, 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.

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.

Recently, the Health Standards Organization (HSO) has been created to develop and maintain standard for healthcare and social services. However, implementation of many standards is not enforced through legislation, though there are organizations and industries that voluntary implement certain standards. Lack of regulatory requirements for implementation of standards and safety best practices may be the reason why healthcare standards are inconsistently applied.

It is acknowledged that there are differences between healthcare delivery, aviation, and nuclear energy with respect to the patient population and resulting variation in practice. However, there are processes in healthcare delivery where safety management system standards could be applied.

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 mandatory 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.
8 References


Federal Aviation Administration, “AC 120-103A - Fatigue Risk Management Systems for Aviation Safety.”


## Appendix A - Charting of Scoping Literature Review Results

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Title</th>
<th>Area of Application</th>
<th>Safety tactics discussed or proposed for implementation in healthcare</th>
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</table>
| Chera et al., 2015 [22] | Improving Patient Safety in Clinical Oncology: Applying Lessons From Normal Accident Theory | Clinical Oncology | **Standardization**  
**Peer Reviews**  
**Hazard Identification (near-miss reporting)**  
The authors introduce Normal Accident Theory (NAT) as a framework, used in aviation and nuclear energy, for better understanding of systems, analyzing their failure potential, and therefore identifying potential hazards and safety concerns. |
| Gabriel et al., 2015 [23] | Incident Learning in Pursuit of High Reliability: Implementing a Comprehensive, Low-Threshold Reporting Program in a Large, Multisite Radiation Oncology Department | Radiation Oncology | **Incident Reporting**  
**Hazard Identification (near-miss reporting)**  
The authors discuss implementation of a low-threshold reporting program to capture and address precursors to adverse events. There are 4 severity levels, levels A to D. Level A is for significant events while level D is for minor events and suggestions for improvement. All incidents within all levels are corrected. However, only incidents categorized in levels A and B thoroughly analyzed. Incidents in levels C and D are logged and trended. |
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<th>Author, Year</th>
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<th>Area of Application</th>
<th>Safety tactics discussed or proposed for implementation in healthcare</th>
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<tr>
<td>Birnbach et al., 2013 [44]</td>
<td>A Framework for Patient Safety: A Defense Nuclear Industry–Based High-Reliability Model</td>
<td>Healthcare</td>
<td><strong>Safety Management Systems</strong>&lt;br&gt;The authors present a safety system framework (based on nuclear energy’s framework) that includes structured processes such as decision making, problem-solving, hazard identification and preventive measures, work planning, and work execution. Seven guiding principles for implementation of a safety management system in healthcare are proposed and are as follows: leadership commitment to create a culture of safety, everyone is accountable and responsible for safety, oversight and enforcement of policies, eliminate sources of error and safety risks that lead to preventable harm, establish a universal and uniform approach to safety management, mandate reporting of near-misses, errors, and safety concerns, and create and maintain a supportive and learning environment.</td>
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<td>Hudson et al., 2012 [24]</td>
<td>Toward Improving Patient Safety Through Voluntary Peer-to-Peer Assessment</td>
<td>Healthcare</td>
<td><strong>Hazard Identification (Peer-to-peer assessments)</strong>&lt;br&gt;A peer-to-peer assessment process (based on nuclear energy safety management concepts) is proposed for implementation in healthcare to facilitate hazard identification and management of latent factors before they lead to adverse events. Reviews in healthcare shall be completed on systems, involve multidisciplinary group of reviewers (preferably from outside of the healthcare organization, be voluntary (units should request to have reviews conducted) and be non-punitive.</td>
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The authors present Probabilistic Risk Assessment (PRA) (also known as Probabilistic Safety Assessment (PSA) or Quantitative Risk Assessment (QRA)) which is an analytical process commonly used in nuclear energy industry and aircraft design to identify all possible modes of failure, consequences and frequency of occurrence. PRA uses complementary tools to facilitate the assessment; these are Event Tree Analysis (ETA) and Fault Tree Analysis (FTA). |
The authors present Sociotechnical Probabilistic Risk Assessment (ST-PRA) which is based on the probabilistic risk assessment (PRA) process explained above. However, ST-PRA considers the contributions of human error and human performance to determine the probability of occurrence of an adverse event. |
| Selby et al., 2018 [34] | Aviation and Procedural Medicine  
Procedural Medicine | Procedural Medicine | **Operational Risk Management** (planning and pre mission-brief to assess risks and decide whether to initiate or cancel a process, operation, or procedure)  
**Sterile cockpit rule** (implementation of fatigue management strategies; includes reducing interruptions, non-essential conversations, elimination of other distractions when a clinician is carrying out critical tasks, and speaking-up when mentally and physically unprepared)  
**Incident/Accident Investigations** (move towards non-punitive reporting and comprehensive investigations to determine the true root-cause of incidents) |
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**Hazard Identification**  
The authors highlight lack of proactive risk management in healthcare delivery and propose a Risk Identification (RID) framework which is a system-based approach to risk identification. This framework includes components such as system mapping and thorough system analysis to identify sources of risks and nature of hazards, risk identification and presentation. |
| Davies et al., 2017 [45] | Can the Aviation Industry be Useful in Teaching Oncology about Safety? | Oncology                              | **Safety Management System**  
The authors propose three aviation safety concepts for application in healthcare. These are: investment in safety, human factors, and development of a comprehensive safety management system. The article also presents an adapted version of aviation safety management system for healthcare which includes the following components philosophy, policy, procedures, practices, products, and performance. |
**Proactive Risk Assessment and Mitigation**  
The author discusses adapting an aviation safety concept called Normal Operations Safety Audit (NOSA) to healthcare. NOSA is a risk management tool which is inspired by systems-thinking and may be used to identify potential sources of error within a system. Observers document processes and analyze them to identify processes or steps where errors occur. |
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| Boussat et al., 2015 [37] | Experience Feedback Committee: A management tool to improve patient safety in mental health | Neuropsychiatry | Incident / Accident Investigations  
The authors propose and discuss implementation of a management tool, Experience Feedback Committee (EFC). EFC is a safety tactic used by aviation where major and minor incident are assessed using a systemic analysis and mitigated accordingly. |
| Scott, De Ziegler, 2013 [38] | Could safety boards provide a valuable tool to enhance the safety of reproductive medicine? | Reproductive Medicine | Incident / Accident Investigations  
The authors propose formation of a national Clinical Safety Board (CSB) to investigate near-misses and adverse events in reproductive medicine. CSBs are inspired by US National Transportation Safety Board (NTSB), an independent and autonomous body of safety experts and investigators. The NTSB investigates all transportation related accidents and incidents including those involving aviation. |
| Lewis et al., 2011 [39] | Counterheroism, common knowledge, and ergonomics: Concepts from aviation that could improve patient safety | Healthcare | Sterile Cockpit  
Standardization (Layouts, IT systems, medical devices)  
Black box Recorder  
Incident / Accident Reporting (Non-punitive)  
Human Factors (Mistake proofing & forcing functions)  
Risk Assessment  
The authors propose use of in-situ simulation as a hazard identification and risk assessment tool. In situ simulation takes place in the actual clinical units where observations may lead to identification of areas of concern, potential hazards, and conflicting standard operating procedures. |
| Hamman et al., 2010 [28] | Using simulation to identify and resolve threats to patient safety | Healthcare | Hazard Identification (In-Situ Simulation)  
Risk Assessment  
The authors propose use of in-situ simulation as a hazard identification and risk assessment tool. In situ simulation takes place in the actual clinical units where observations may lead to identification of areas of concern, potential hazards, and conflicting standard operating procedures. |
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| Pham et al., 2010 [35] | Recasting the RCA: An improved model for performing root cause analyses | General                   | Incident / Accident Investigations (Root-Cause Analysis) Risk Assessment  
The authors propose a Root-Cause Analysis (RCA) framework based on the processes used by the Commercial Aviation Safety Team (CAST). CAST investigates aviation incidents and proposes appropriate risk controls. The proposed RCA framework includes analysis of the event that happened and why it happened, identifying and prioritizing the factors that caused harm, and evaluating the probability that the identified factors would cause harm in the future. Following the identification of the root-cause and the contributing factors, the investigation team recommends several risk controls and ranks them based on their level of effectiveness. A separate implementation team develops plans for implementation of proposed risk controls. |
| Callaghan et al, 2010 [40] | Making ‘safety’ the focus of investigations into adverse events in health care | Healthcare                 | Incident / Accident Investigations  
Proposes an independent central safety investigation agency, based on aviation’s independent investigation agency, to investigate adverse events in health care. |
| Hamman et al, 2009 [29] | Using In Situ Simulation to Identify and Resolve Latent Environmental Threats to Patient Safety: Case Study Involving a Labor and Delivery Ward | Labour and Delivery Ward    | Hazard Identification (In-Situ Simulation)  
Use of in situ simulation (a tool used by aviation to identify hazards and latent threats) as a team training tool and a hazard identification tool to identify, assess, and control latent environmental threats to patient safety. The article presents results of a 4 scenario in situ simulation which led to identification of 6 latent threats in a US hospital labor and delivery ward. |
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Risk Management  
The authors propose formation and implementation of a team similar to Commercial Aviation Safety Team (CAST) in healthcare to investigate incidents, and implement robust and strong risk control strategies. The proposed model is called public private partnership to promote patient safety (P5S). |
Present a framework that helps create a system safety architecture for processes/units in a healthcare setting through defining all operational systems and subsystems followed by completion of a safety assessment and risk-prioritization.  
Operational Risk Management  
Use of a framework from aviation called “Airline Transport Oversight System” or ATOS to identify systems, sub-systems, processes, and elements. This breakdown facilitates analysis and assessment of systems, sub-systems, processes, and elements related to operational risk management. Recommends implementation of a safety management system. |
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Hazard Identification  
Risk Management  
Human Factors (Error Management)  
The authors discuss use of Human Error Risk Management for Engineered Systems (HERMES) methodology, interface of humans with the elements of a system (aviation’s SHELL model), root-cause analysis, and risk assessment. Data, prospective, retrospective, and real-time, can be gathered and analyzed to identify human-machine interactions and potential sources of error. |
| ElBardissi et al., 2007 [42] | Application of the Human Factors Analysis and Classification System Methodology to the Cardiovascular Surgery Operating Room | Cardiovascular Surgery | Human Factors (Error Management)  
This article discusses the application of Human Factors Analysis and Classification System methodology to identify sources of error and factors that may lead to errors within the operating room. |
| Singh et al., 2006 [2] | Understanding diagnostic errors in medicine: a lesson from aviation | General | Error Management (Situational Awareness)  
The authors recommend the use of the situational awareness framework commonly used in aviation industry and its application in medicine to manage errors and prevent diagnostic errors. |
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| Wilf-Miron et al., 2003 [31] | From aviation to medicine: applying concepts of aviation safety to risk management in ambulatory care | Ambulatory Care     | **Risk Management**  
**Human Factors (Error Proofing, Standardization)**  
**Hazard Identification (Near Miss Reporting)**  
**Incident / Accident Reporting & Investigations (Non-punitive)**  
The authors present a set of principles that forms a framework for aviation style risk management. The principles are focused on error proof systems (achieved by standardization and redundancy), non-punitive adverse event investigations, systems approach, debriefing of all events including near-misses (near-misses have potential to identify sources of error and hazards), permanent risk analysis and mitigation program which includes communication of safety incidents. |
| Hudson, 2003 [41]  | Applying the lessons of high-risk industries to healthcare           | Healthcare          | **Safety Management Systems**  
**Incident / Accident Investigations**                                                                                                                                                                                                                                 |
# Appendix B - Summary of Aviation Regulations and Standards Publications

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<tr>
<th>Publishing Organization</th>
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<td><strong>International Civil Aviation Organization (ICAO)</strong></td>
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<td>Annex 6 - Operation of Aircraft - Part I - International Commercial Aviation – Aeroplanes [46]</td>
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<td>Annex 6 - Operation of Aircraft - Part II - International General Aviation – Aeroplanes [47]</td>
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<td>Annex 8 - Airworthiness of Aircraft [51]</td>
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<td>Annex 13 - Aircraft Accident and Incident Investigation [49]</td>
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<td>Annex 14 - Aerodromes - Volume I - Aerodromes Design and Operations [50]</td>
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<td>Annex 19 - Safety Management [48]</td>
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<td>Doc 9859 Safety Management Manual [52]</td>
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<td>Doc 9966 Manual for the Oversight of Fatigue Management Approaches [53]</td>
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<td>Fatigue Management Guide for Airline Operators [54]</td>
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<td>Fatigue Management Guide for Air Traffic Service Providers [55]</td>
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<td>SOR/96-433 Canadian Aviation Regulations [56]</td>
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<td>Advisory Circular (AC) No. 107-001 - Guidance on Safety Management System Development [57]</td>
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<td>TP14572 Fatigue Risk Management System (FRMS) for the Canadian Aviation Industry: An Introduction to Managing Fatigue [58]</td>
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<td>TP 14573 - Fatigue Risk Management System for the Canadian Aviation Industry - Fatigue Management Strategies for Employees [59]</td>
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<td>TP 14575 - Fatigue Risk Management System for the Canadian Aviation Industry - Developing and Implementing a Fatigue Risk Management System [60]</td>
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<td>Fatigue Risk Management System (FRMS) Toolbox [61]</td>
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<td>Transportation Safety Board (TSB)</td>
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<td>SOR/2014-37 Transportation Safety Board Regulation [63]</td>
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<td>United States of America</td>
<td>Electronic Code of Federal Regulation (eCFR) Title 14 - Aeronautics and Space [64]</td>
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<td>AC 120-103A Fatigue Risk Management Systems for Aviation Safety [65]</td>
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### Appendix C - Summary of Nuclear Energy Regulations and Standards Publications

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<td>Governmental, Legal, and Regulatory Framework for Safety - General Safety Requirements - No. GSR Part 1 (Rev. 1) [68]</td>
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<td>Leadership and Management for Safety - General Safety Requirements - GSR Part 2 [69]</td>
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<td>Safety Assessment for Facilities and Activities - General Safety Requirements - No. GSR Part 4 (Rev. 1) [70]</td>
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<td>Safety of Nuclear Power Plants - Design - Specific Safety Requirements - No. SSR-2/1 (Rev. 1) [71]</td>
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<td>Safety of Nuclear Power Plants - Commissioning and Operation - Specific Safety Requirements - No. SSR-2/2 (Rev. 1) [72]</td>
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<td>Human Factors Engineering in the Design of Nuclear Power Plants - Specific Safety Guide - No. SSG-51 [73]</td>
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<td>Modifications to Nuclear Power Plants - Safety Guide - No. NS-G-2.3 [74]</td>
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<td>Conduct of Operations at Nuclear Power Plants - Safety Guide - No. NS-G-2.14 [75]</td>
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<td>Periodic Safety Review for Nuclear Power Plants - Specific Safety Guide - No. SSG-25 [76]</td>
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<td>Operating Experience Feedback for Nuclear Installations - Specific Safety Guide - No. SSG-50 [77]</td>
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<td>The Management System for Nuclear Installations - Safety Guide [78]</td>
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<td><strong>Canadian Nuclear Safety Commission (CNSC)</strong></td>
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<td>Nuclear Safety and Control Act [79]</td>
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<td>General Nuclear Safety and Control Regulations (SOR/2000-202) [81]</td>
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Appendix D - Summary of Healthcare Regulations and Standards Publications

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<td>Institute (CPSI)</td>
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Appendix E - Interview Questionnaire

**Process Control:**

1. Are engineering design control components such as process control, validation, and verification implemented in your organization to ensure operations are safe, consistent, and repeatable?

2. What were the benefits and challenges of implementing these processes?

**Change Control**

1. Are there formal change control processes implemented in your organization to evaluate, validate and control operational and equipment changes?

2. Question 4: How are changes to operations and equipment evaluated and managed in your organization? Is there a change control approval body or board?

3. Question 5: What were the benefits and challenges of implementing a change control committee and process?

**Investigations**

1. How well are corrective and preventive actions implemented in your organization, monitored and evaluated for effectiveness in eliminating or reducing safety hazards?

2. Are there any challenges in monitoring the effectiveness of corrective actions?

**Safety Management Systems**

1. What hazard identification and risk assessment techniques are used in your organization?

2. What are some of the challenges of proactive hazard identification methods?

3. Does your organization consider human fatigue a safety hazard?

4. What are some of the challenges of self-reporting and fatigue self-regulation? Any
challenges with taking fatigue into account during risk assessment or event investigation processes?

**Root Cause Analysis and Risk Controls**

1. What types of hazard control techniques are most commonly implemented in your organization to ensure that incidents/accidents do not recur or that the risks associated with them are reduced?

2. What are some of the implementation challenges associated with substitution, elimination, and engineering hazard controls?

**Reliability**

1. How is operational reliability achieved in your organization?

**Worker Fatigue & Incidents**

1. What are some fatigue management practices in your organization and is worker fatigue ever considered as a potential root-cause to adverse events?
Appendix F - Overview of State Safety Programme (SSP) Requirements

An SSP shall include [46], [48], [50]–[52]:

1. State safety policy and objectives
   a. State safety legislative framework
   b. State safety responsibilities and accountabilities
   c. Accident and incident investigation
   d. Enforcement policy

2. State safety risk management
   a. Safety requirements for the service provider’s SMS
   b. Agreement on the service provider’s safety performance

3. State safety assurance; and
   a. Safety oversight
   b. Safety data collection, analysis and exchange
   c. Safety-data-driven targeting of oversight of areas of greater concern or need

4. State safety promotion
   a. Internal training, communication and dissemination of safety information
   b. External training, communication and dissemination of safety information